AD-A239 346

OCUMENTATION PAGE

(1)

AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	May 1991	THESIS/DISSERTATION

4. TITLE AND SUBTITLE

In Vitro Determination of the Accuracy and Precision of an Infrared Tympanic Thermometer

5. FUNDING NUMBERS

6. AUTHOR(S)

Kelly J. Scherbenske, First Lieutenant

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

AFIT Student Attending: University of Texas

8. PERFORMING ORGANIZATION REPORT NUMBER

AFIT/CI/CIA- 91-044

9. SPONSORING MONITORING AGENCY NAME(S) AND ADDRESS(ES)

AFIT/CI
Wright-Patterson AFB OH 45433-6583

10. SPONSORING MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION AVAILABILITY STATEMENT

Approved for Public Release IAW 190-1
Distributed Unlimited
ERNEST A. HAYGOOD, 1st Lt, USAF
Executive Officer

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

14. SUBJECT TERMS

15. NUMBER OF PAGES
103

16. PRICE CODE

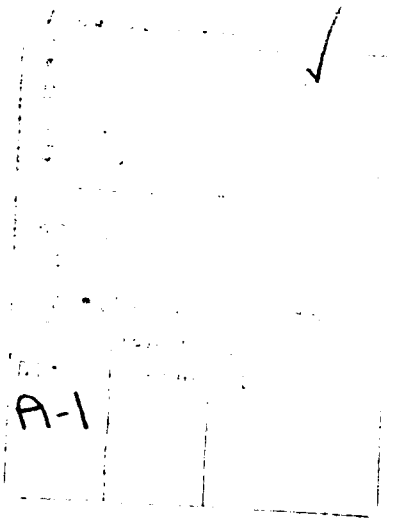
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

IN VITRO DETERMINATION OF THE ACCURACY AND PRECISION OF AN INFRARED TYMPANIC THERMOMETER

A

THESIS

Presented to the Faculty of The University
of Texas Graduate School of Biomedical Sciences
at San Antonio
in Partial Fulfillment
of the Requirements
for the Degree of
MASTER OF SCIENCE IN NURSING



By
Kelly Jeanette Scherbenske, RN, BSN

San Antonio, Texas

May 1991

IN VITRO DETERMINATION OF THE ACCURACY AND PRECISION OF AN INFRARED TYMPANIC THERMOMETER

Kelly J. Scherbenske

APPROVED:

Supervising Professor

Date

APPROVED:

Sanford A. Miller, Ph.D.
Dean

ACKNOWLEDGEMENTS

The author appreciates the opportunity provided by the United States Air Force Nurse Corps to attend graduate school at the University of Texas Health Science Center at San Antonio.

The author expresses the deepest appreciation to Carol Ledbetter, Ph.D. for her encouragement, guidance, and enthusiasm throughout the study. Special appreciation also goes to Terri Schwab, Ph.D. for her help and support. The concerted efforts of Doctors Ledbetter and Schwab throughout the entire study, from proposal development through oral defense, made this a most enjoyable learning experience.

Special thanks are extended to Sondra Perdue, Ph.D. for assistance in statistical planning and analysis.

Special thanks are also extended to Jo Ann Crow, Ph.D., Marilyn Murphy, Ph.D., and Judith Shockley, MSN, for their expert consultations and assistance.

The author appreciates the efforts of Lt Col (Dr) Wayne Patterson and the staff at the Clinical Investigations Facility, Wilford Hall Medical Center, San Antonio, Texas.

IN VITRO DETERMINATION OF THE ACCURACY AND PRECISION OF AN INFRARED TYMPANIC THERMOMETER

Publication No. _____

Kelly Jeanette Scherbenske, MSN

The University of Texas Graduate School of Biomedical Sciences
at San Antonio

Supervising Professors: Carol Ledbetter, R.N., Ph.D.
Terri Schwab, R.N., Ph.D.

The purpose of this study was to determine the in vitro accuracy and precision of two FirstTemp^{R} Infrared Tympanic Thermometers (ITT) and the Diatek oral probe. The in vitro environment was an airtight, closed circuit, continuously circulating water bath. Bath temperature was monitored with a glass mercury

thermometer (GMT) traceable to the National Bureau of Standards.

Accuracy was established by determining the residual differences between each device and the glass mercury thermometer, across a temperature range of 34.0° to 40.0°C. Scatter plots were analyzed to determine consistency and bias.

The ITT lost accuracy outside a narrow temperature range of 35.5° to 38.5°C; the oral probe maintained accuracy and a consistent bias of + 0.2°C across the temperature range of 34.0° to 40.0°C. The ITT had a limited accurate clinical range of 35.5° to 38.5°C. The Diatek oral probe maintained accuracy across a wider clinical temperature range of 34.0° to 40.0°C.

TABLE OF CONTENTS

Appendices

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

Introduction

Overview

Which temperature site is best representative of core body temperature? Through history, this question has remained unsolved and is in need of further research. The validity of the temperature readings depends on "the use of an appropriate site, a dependable thermometer, and a proper technique" (Erickson, 1980, p.157).

When referring to body temperature, we usually speak of deep (core) temperature, rather than the tissue or skin temperature. There are several sites available that reflect the core temperature - oral cavity, esophagus, and rectum. However, the "true" core temperature is measured in the pulmonary artery, where the temperature is a "balance between heat production in the body and heat loss in the body" (Bligh, 1973, p.80).

Temperature measurement has been possible since the 1700s. A great variety of temperature measuring devices are available, including: glass-mercury thermometers, liquid crystal thermometers, rectal thermistors, bladder thermistors, pulmonary artery

catheter thermistors, and esophageal thermistor thermometers (Shinozaki, Deane, & Perkins, 1988). Most of these devices can only be used in certain settings, and each has inherent problems with its use.

In the early 1960s, Benzinger measured temperature changes at the tympanic membrane. The tympanic membrane is situated at the immediate vicinity of the internal carotid artery, which also supplies the hypothalamus. Core body temperature is regulated primarily by central nervous system feedback mechanisms which operate through the hypothalamus. Thus, theoretically, the tympanic membrane is a potential site for core temperature measurements (Benzinger, 1969).

The tympanic membrane has been used as a site for measurement of core temperature for many years in anesthesia, using indwelling contact-type probes. However, the use of these indwelling contact-type tympanic membrane probes is limited because they are uncomfortable and potentially dangerous. Possible dangers include trauma to the external auditory canal with subsequent otitis externa, oozing from the ear, and perforation of the tympanic membrane (Wallace, Marks, Adkins, & Mahaffey, 1974).

In the late 1980s, the infrared tympanic thermometer (ITT) was introduced. The ITT is an infrared auditory canal probe. The problems inherent in oral, rectal, esophageal, and pulmonary artery temperature measurement may not exist with the ITT. The ITT is noninvasive, nontraumatic, easy to use, convenient, provides a temperature reading in less than two seconds, and can be used on neonates, children and adults in any setting (Shinozaki et al., 1988; Terndrup, Allegra, & Kealy, 1989).

Need for the Study

Temperature measurement is a common nursing procedure, and is an "important observation in assessing a person's state of health" (Erickson, 1980, p. 157). Technological advances have allowed health care professionals to measure temperature using various devices, at various sites. Regardless of the device or site used, the "overall goal is to obtain an accurate temperature as safely and conveniently as possible" (Barber & Kilmon, 1989).

The requirements of a suitable site for measuring core temperature, according to Shiraki, Konda and Sagawa (1986), are as follows: "(1) Measurement should be convenient, harmless, and painless; (2) temperature

at the site should not be directly influenced by environmental temperature changes; and, (3) temperature changes should reflect, quantitatively and rapidly, small changes in blood temperature [core temperature]" (p.98).

The oral and rectal routes are the most common sites for core temperature measurement; and the glass mercury thermometer and electronic probes are the most often used devices. These sites and devices, however, have several problems associated with them. The use of the rectal site is inconvenient, embarrassing for the patient, and cannot be used on all patient populations (Shinozaki et al., 1988; Terndrup et al., 1989). The accuracy of the glass mercury thermometer has been questioned; results can be affected by placement, insertion technique, and length of placement time. Electronic devices also present problems with proper placement and can serve as a source of cross-contamination (Baker, Cerone, Gaze, & Knapp, 1984; Erickson, 1980).

The electronic probes are ubiquitous, and are the accepted standard measure of temperature in clinical settings. Despite this fact, they have not been subjected by the nursing research community to studies

which evaluate validity and reliability issues. According to Gift (1988), "reliability and validity are reported for behavioral measures used in nursing research but less often are reported for physiologic measures or for measures commonly taken in the clinical setting" (p. 128).

The most representative site of core temperature is the blood in the pulmonary artery (Bligh, 1973). However, the use is limited because it is invasive, potentially dangerous, a potential source of infection, and can only be used in the intensive care unit and operating room settings (Shellock & Rubin, 1982).

According to Intelligent Medical Systems, the manufacturers of FirstTemp^{R}, the infrared tympanic thermometer (ITT) offers several advantages over the more conventional methods of temperature monitoring. The external auditory meatus provides a convenient and dry site, is acceptable by most patients, and is not a source of cross-contamination. Using the ITT, the procedure is noninvasive and can be performed within two seconds (Shinozaki et al., 1988; Terndrup et al., 1989).

The introduction of the ITT has stimulated a new direction for nursing research. The purpose of this

research is evaluation of a product which measures physiologic events having direct implications for treatment protocols. A doctorally prepared statistical scientist was consulted during the development of a study design that would allow a comparison of the ITT to a known standard and to instruments already in use, and appropriate statistical analysis to determine precision and accuracy of the infrared tympanic thermometer.

The ITT should be compared to two different standards; the National Bureau of Standards glass mercury thermometer, a "known standard or true value" (Gassert, 1990, p. 18), and to an electronic digital thermometer, the accepted standard measure of temperature in clinical settings. Including an electronic digital thermometer is advantageous for two reasons: (a) To control researcher bias by simultaneously testing both the ITT and the electronic digital thermometer in the same environment; and (b) to determine the "accepted" accuracy of a device already in clinical use for the measurement of temperature.

"An ideal measuring instrument is one that results in measures that are relevant, accurate, unbiased, sensitive, unidimensional, and efficient" (Polit &

Hungler, 1987, p. 313). In this case, measurement is concerned with the methods used to collect valid and reliable temperature data. Inaccuracies that are present in the measurement process may result in errors of temperature measurement. Errors in measurement contribute to inaccurate results which would effect patient care.

Accuracy (validity) and precision (reliability) issues related to physiologic measures are two important components in the research process. If accuracy (validity) and precision (reliability) have not been established, the study results must be interpreted with a degree of skepticism.

Purpose

The purpose of this study was to determine the in vitro accuracy (validity) and precision (reliability) of the FirstTemp^{R} Infrared Tympanic Thermometer when compared to a glass mercury thermometer traceable to the National Bureau of Standards?

Research Questions

1. What is the accuracy (validity) of the FirstTemp^{R} ITT and the Diatek oral probe, when compared with a glass mercury thermometer (National Bureau of Standards), tested in an in vitro environment across a

temperature range of 34.0° - 40.0°C ?

2. What is the reproducibility of the FirstTemp^{R} ITT and the Diatek oral probe as measured in an in vitro environment across a temperature range of 34.0° - 40.0°C ?

Definition of Terms

Accuracy. "The term to describe validity for physiologic measures is accuracy, which has been described as the difference between the measured value and the true value. Accuracy of physiologic measures is most often established by comparing the measured value to a standard, usually that maintained by the National Bureau of Standards laboratory, in Washington, D.C., or the International Standards Laboratory in Sèvres, France" (Gift, 1988, p.129). In this study, accuracy was defined as the residual difference, or the difference between the FirstTemp^{R} infrared tympanic thermometer and the glass mercury thermometer, and the difference between the Diatek oral probe and the glass mercury thermometer.

Ambient condition. Surrounding, environmental temperature and humidity. Measurements in this study were made with a temperature and relative humidity device by Omega Engineering, Incorporated (Model RH -

21F, Serial Number 201-87-05630).

Artificial auditory canal. A dry, airtight "canal" made of Travenol plastic tubing. The inside diameter of the tubing was 9 mm and the tubing length was 3 cm (see Appendix A). The internal end of the plastic tubing was sealed with a surgeon's glove stretched thinly over the end, and was completely submerged in the water bath. The external end of the tubing was open. The ITT probe sealed the external opening of the artificial auditory canal.

Calibration. Refers to "the process of comparing a measurement to a known standard or true value" (Gassert, 1990, p. 18). In this study, calibration refers to comparing the FirstTemp^{R} infrared tympanic thermometer and the Diatek oral probe to the glass mercury thermometer (see Appendix B).

Core temperature. "The term usually relates to a representative core temperature obtained by placing a thermometric instrument in a natural orifice (e.g. rectum, mouth, vagina, oesophagus, external auditory meatus), which should always be specified" (Bligh, 1973, p. 79). In the context of this study and "...thermoregulation, the most significant single body [core] temperature is probably that of the arterial

blood leaving the heart" (Bligh, 1973, p. 92).

Electronic thermometer (ET). The Diatek oral probe. The residual difference between the Diatek oral probe and the Dekabox Decade Resistor DB 62 during biomedical calibration was + 0.1° to + 0.2°C (Identification number WHMC 32741; see Appendix C).

Equilibration time. The amount of time the in vitro environment required to stabilize and remain constant when increased in 0.5°C increments (see Appendix D).

Glass mercury thermometer (GMT). A liquid-in-glass thermometer calibrated against standards certified by the National Bureau of Standards with scale range 25.0° to 55.0°C in 0.1°C divisions with auxiliary scale at 0°C (Standard Serial Number 128239, NBS Identification Number 88024; see Appendix B).

Infrared tympanic thermometer (ITT). FirstTemp^{R} Model 2000 aural thermometer, manufactured by Intelligent Medical Systems (see Appendix E). An electronic thermometer which uses a sensor placed in an otoscope like probe that is held at the external auditory meatus to measure the infrared radiation emitted from the tympanic membrane (Serial Number ITT A 23344, Serial Number ITT B 30616).

In vitro environment. "In an artificial environment outside the living organism [New Latin, 'in glass']" (Morris, 1976, p.689). The in vitro environment (see Appendix F) was an airtight, insulated, closed circuit 21.6 cm x 15 cm x 8.9 cm continuously circulating water bath (see Appendix G). Bath temperature was monitored with a glass mercury thermometer traceable to the National Bureau of Standards, scaled to 0.1°C.

Precision (reliability). "Describes the reproducibility, or consistency, of measurements made by a physiologic instrument" (Gift, 1988, p. 130). In this study, precision was determined by testing each device three times at each temperature across a temperature range of 34.0° - 40.0°C.

Reproducibility. Consistency at each temperature increment, as measured in an in vitro environment across a temperature range of 34.0° - 40.0°C. Each device was tested three times at each temperature, within a three minute time interval.

Assumptions

1. The glass mercury thermometer (GMT) traceable to the National Bureau of Standards was accurate (valid) and precise (reliable).

2. In vitro calibration, using an airtight, insulated, closed circuit, continuously circulating water bath, was an accurate means of determining instrumentation accuracy (validity) and precision (reliability).

3. All equipment was calibrated immediately prior to data collection according to manufacturer instructions.

4. The ITT was calibrated by Intelligent Medical Systems prior to data collection.

Limitations

1. The artificial in vitro environment may not reflect natural body orifices (e.g. auditory canal and mouth).

2. The reading of the glass mercury thermometer was by the human eye, and was subject to bias by the primary investigator and research assistant.

CHAPTER II

Review of the Literature

Theoretical Framework

Which body temperature is of greatest significance in thermoregulation? "Thermoregulation refers to internal control of body temperature" (Kinney, Packa, & Dunbar, 1988, p. 415). Choosing a representative and meaningful core temperature in thermoregulatory studies is important - and is of considerable controversy. In many studies, particularly on humans, it is also a matter of practicality.

Body temperature is a measure of the balance of heat production and heat loss in the body. Heat production and heat loss are coordinated by the autonomic and neuroendocrine systems, with the hypothalamus acting as the thermostatic control center. Heat production (metabolism of food, disease states, and muscle activity) and heat loss (radiation, conduction, convection and evaporation) are balanced in health to maintain the narrow range of normal: 36^{o} - 37.5^{o}C (Guyton, 1986; Kinney et al., 1988).

The extremely narrow range of human body temperature compatible with life is well known. As a homeotherm, humans are capable of maintaining core body

temperature at a near constant state, demonstrating a diurnal variation that fluctuates only within 0.5^{o} - 1.0^{o}C. This narrow range is maintained in extremes in climate, increased or decreased metabolism, or skeletal muscle activity (Guyton, 1986; Kinney et al., 1988).

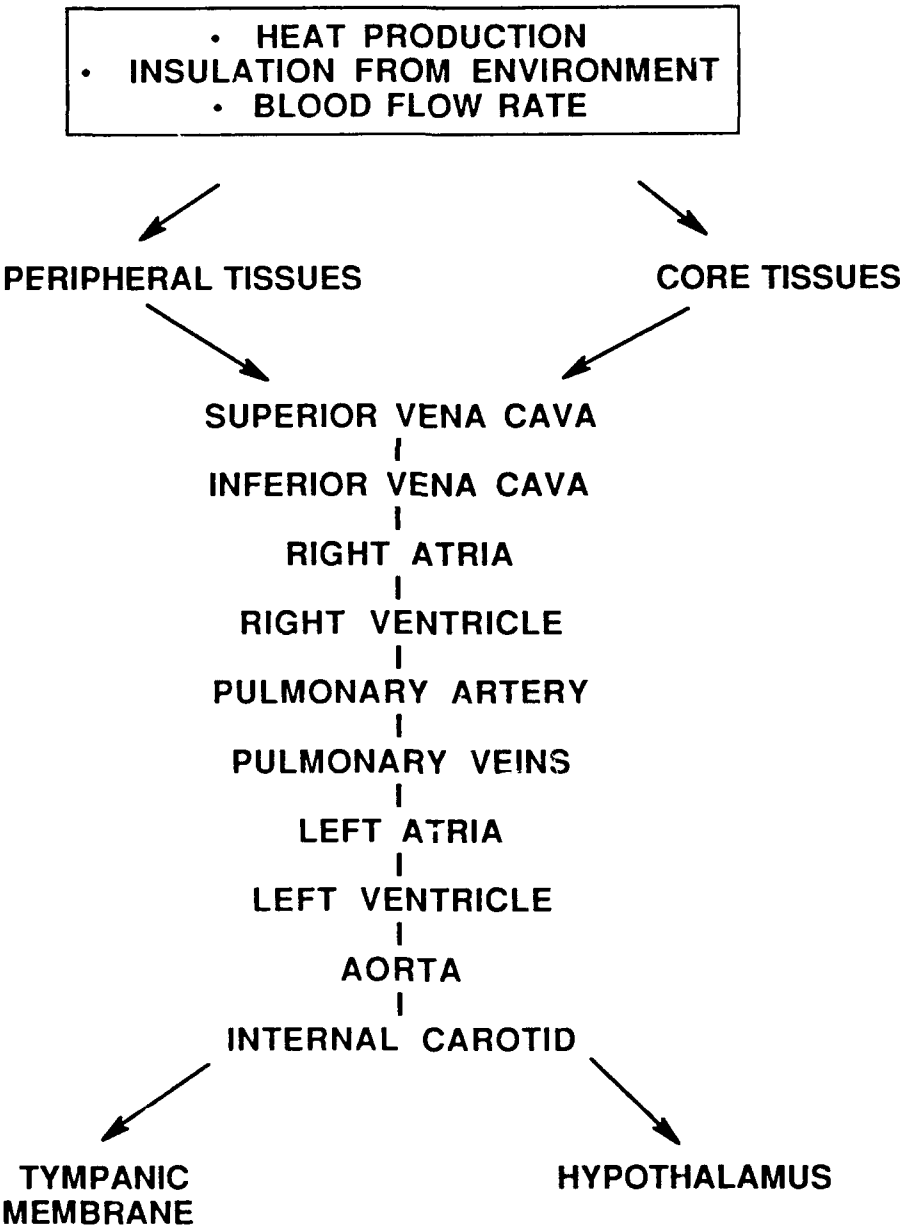
When referring to body temperature, we are usually referring to deep core temperature rather than skin or tissue temperature (see Figure 1). Skin temperature fluctuates with the rise and fall of the surrounding environmental temperature. The temperature of a tissue or organ reflects its own heat production, its insulation from the environment, and the flow rate of the blood perfusing it (Bligh, 1973; Guyton, 1986; Kinney et al., 1988).

In terms of thermoregulation, the most significant single body temperature is probably that of the blood in the pulmonary artery. According to Bligh (1973):

> The venous return to the right side of the heart can be considered as having two principal thermal components: that draining from core tissues which are more involved in heat production within the body than in heat loss from the body, and that draining from peripheral tissues which are more involved in

FIGURE 1

Theoretical Framework



heat loss from the body than in heat production (p.80).

The blood in the pulmonary artery reflects any change in the balance between heat production and heat loss.

The blood in the pulmonary artery cannot be measured without the invasive placement of a pulmonary artery catheter. Thus, temperatures within natural orifices are most frequently used. Rectal temperature is often used for measurement of core temperature and is 0.2^{o} - 0.6^{o}C higher than the blood leaving the left side of the heart (Bligh, 1973) and approximately 0.6^{o}C higher than oral temperature (Guyton, 1986).

Both deep esophageal and tympanic temperature are reasonably accurate indicators of core temperature. Deep esophageal temperature is the closest approximation to the temperature of the blood leaving the heart (Bligh, 1973). Since the tympanic membrane and the hypothalamus are supplied by the internal carotid artery, the tympanic membrane temperature is an accurate indication of the blood supplying the hypothalamus and influencing the hypothalamic temperature sensors (Baker, Stocking, & Meehan, 1972; Benzinger, 1969; Bligh, 1973).

The hypothalamus is considered to be the

thermostatic control center for the human body. Thus, measuring hypothalamic temperature is important when addressing thermal physiology.

A study by Baker et al. (1972) investigated simultaneous measurements of hypothalamic temperature and tympanic membrane temperature in two cats and one monkey. Thermocouples had been surgically implanted at the two sites in each animal. The changes that occur in hypothalamic temperature during feeding, sleeping, and arousal, were accompanied by similar changes in the tympanic temperature. It was concluded that "changes in arterial blood temperature affect the hypothalamus and the tympanic membrane in the same way and that the tympanic temperature is a good index of hypothalamic temperature" (p. 739).

Since it is clinically impossible to measure hypothalamic temperature directly in humans, the tympanic membrane was identified as an accessible site reflective of hypothalamic temperature. Benzinger (1969) was the first to use the tympanic membrane for measuring temperature.

> Our site of choice for the measurement of central temperature was the tympanic membrane of the ear, located midway between the surface

> of the head and the saggital midplane, close to the stem of the internal carotid artery (the mainline of blood supply to the brain including the thermoregulatory centers), accessible by suitable probes, without discomfort, always dry, and lending itself to thermoelectric measurements with clean, disposable sensors (p. 1202).

When Benzinger (1963) began using the tympanic membrane temperature to reflect hypothalamic temperature, it was assumed that the temperature of an internal body site is determined by (a) the temperature of the arterial blood perfusing the site, (b) the rate of blood flow through the site, and (c) the rate of metabolic heat production at the site. Benzinger reasoned that because the hypothalamus and the tympanic membrane both receive blood from the internal carotid artery, then changes in arterial blood temperature would affect both sites in the same way. The animal study by Baker et al. (1972) supported Benzinger's prediction; similar temperature shifts occurred in the hypothalamus and at the tympanic membrane.

Review of the Literature

Overview. Until recently, the use of the tympanic membrane (TM) for temperature measurement has been limited to anesthesia. The TM has been used as a site for the measurement of core temperatures in anesthesia for several decades. The majority of research in the area of measuring temperatures has dealt with conventional methods. The means of obtaining body temperature measurements include central core (e.g. esophageal or Swan-Ganz catheter), axillary, oral, rectal, bladder, and the recently released infrared auditory canal probes (Terndrup, Allegra, & Kealy, 1989).

Benzinger (1969) was the first to use the tympanic membrane temperature in studies of thermoregulation in man. An indwelling auditory canal sensor, in direct contact with the tympanic membrane, was used on anesthetized patients. The tympanic measurements in this study "ran parallel to the readings of an ideally placed esophageal probe. The difference between the two probes is small and quite constant, the eardrum usually reading lower by 0.2^{o}C" (p. 1208).

In the late 1980s, the Infrared Tympanic Thermometer (ITT) was introduced for use in clinical

practice. The ITT is an instrument that looks like an otoscope and has a probe covered with a disposable speculum. When placed in the external auditory meatus, the sensor gathers emitted infrared energy absorbed by the tympanic membrane and displays the tympanic surface temperature. Theoretically, the TM is an acceptable site for assessment of core temperature because the tympanic membrane shares the same blood supply that reaches the thermoregulatory portion of the hypothalamus (Benzinger, 1969).

A review of the literature at the University of Texas Health Science Center at San Antonio library (Medline, CINAHL, and Index Medicus) revealed limited research upon which to base adoption of the ITT for clinical practice. Although much has been written concerning tympanic membrane temperatures, there were only four research studies reported in the literature dealing specifically with the ITT (Erickson, 1990; Ros, 1989; Shinozaki, Deane, & Perkins, 1988; Terndrup et al., 1989). The scope of these four studies were limited and the results conflicting.

RESEARCH: ITT. Three of the four studies suggested that the ITT can accurately measure temperature (Erickson, 1990; Shinozaki et al., 1988;

Terndrup et al., 1989). The most recent of these three studies was conducted by Erickson.

Erickson (1990) examined the relationship between tympanic and oral temperatures in adults having major abdominal surgery (n = 60). Tympanic temperature was measured with an infrared tympanic thermometer and oral temperature with a "predictive thermistor thermometer."

Erickson (1990) reported:

> Tympanic and oral temperatures correlated well at each time (r = .77 - .85). Mean tympanic readings were higher than oral ones by 1.1 - 1.5°F. An analysis of variance indicated that the tympanic-oral temperature difference did not vary significantly except at PACU [Post Anesthesia Care Unit] exit, but the change was small and of limited clinical importance. The findings suggest that either site could be used for intermittent body temperature monitoring, although a single site should be used in a given individual (p. 305).

The findings reported by Erickson (1990) are difficult to interpret because little information about the study design, instrument calibration, and sample is included

in the abstract.

In 1989, Terndrup et al. tested the influence of iced water, hot water, and smoking on oral, rectal, and FirstTemp^{R}, tympanic membrane-derived (TMD) temperature measurements over time. The study also tested the accuracy and reproducibility of the TMD with simultaneous oral and rectal temperature measurements.

The sample consisted of 12 male and 10 female volunteers (n = 22); the mean age was 33.4 years. Criteria for exclusion from the study were illness or ingestion of any medications which affect body temperature within two weeks prior to data collection. Oral and rectal temperatures were measured with digital electronic probes (Survalent Electronic Thermometer) and the TMD temperatures were measured with the FirstTemp^{R} infrared tympanic thermometer (Terndrup et al., 1989).

Baseline temperatures, including bilateral TMD, rectal, and oral temperatures were measured after the subjects remained NPO for 30 minutes. The subjects then drank six ounces (180 ML) of iced water ($0.0^{O} \pm 0.5^{O}C$). Simultaneous tympanic and oral membrane temperatures were obtained at 1.5, 3, 5, 7, 9, 11, 13, and 15 minutes after beginning the ingestion. The

subjects then undertook a 15 to 30 minute washout period, during which time they were NPO and remained at rest. An identical series of temperature (TMD and oral) measurements were obtained after the subjects drank six ounces of hot water ($46.0^{o} \pm 2.0^{o}C$). Following another 15 to 30 minute washout period, seven subjects consented to smoke. Temperatures were measured at the same time intervals as drinking the cold and hot liquids. The average change in temperature from baseline $\pm$ Standard Error of the Mean (SEM), for both TMD and oral temperatures, was plotted as a function of time (Terndrup et al., 1989).

In the second part of their study, comparisons were made between 107 pairs of TMD and rectal temperature measurements. The TMD and rectal temperatures were obtained from a nonrandom sample of emergency department and hospitalized patients (n = 100). The sample consisted of 51 males and 49 females with an age range of one month to 85 years; mean age of 26.5 years. A convenience sample was used in the study because rectal temperatures had already been obtained within 30 minutes of the presence of one of the data collectors. A regression line and correlation coefficient were calculated for TMD versus rectal

temperature (Terndrup et al., 1989).

The mean rectal temperature showed no clinically significant change over time: initial, $37.1^{o} \pm 0.1^{o}C$ (mean $\pm$ SEM); final, $36.8^{o} + 0.11^{o}C$ ($p > 0.10$). The mean change in oral temperature after ingestion of iced or hot water was significant (test and probability). The change was greatest immediately after the subject drank the cold or hot water and approached baseline over the 15 minute interval of temperature measurement. The significant decrease in mean oral temperature following the iced water ingestion persisted for five minutes, whereas a significant increase in oral temperature following the hot water ingestion persisted for at least seven minutes. No significant changes occurred with cigarette smoking. No significant change in the TMD temperature measurements occurred with ingestion of liquids or cigarette smoking. The correlation coefficient for the TMD and rectal temperatures was 0.90, $p < .001$ (Terndrup et al., 1989).

Ten patients were diagnosed with acute otitis media (AOM). The correlation coefficient for the AOM subjects (TMD versus rectal temperature) was 0.84, $p < .001$ (Terndrup et al., 1989).

The conclusions drawn by Terndrup et al. (1989) suggest that the ITT is easy to use, is unaffected by examiner technique, is reproducible, and is unaffected by small-volume ingestion of cold or hot liquids or smoking. This study is limited by the small range of temperature values, small sample size of smokers (n = 7), lack of inter-rater reliability, and no mention of instrumentation calibration.

Shinozaki et al. (1988) evaluated a prototype of an ITT (FirstTemp^{R}) against core temperature measured by the thermistor tip of a pulmonary artery catheter (PAC) and a rectal probe (RP) in vivo. In vitro calibration for accuracy of the three instruments was performed against a thermometer traceable to the Bureau of Standards.

The results of the in vitro calibration suggest that all three instruments are capable of accurately measuring temperature. The standard deviation, at any given temperature, was never more than 0.13^{o}C. The PAC was used as the benchmark for the in vivo study because it had the smallest variance and paralleled closest to the water bath temperature (Shinozaki et al., 1988).

The in vivo study was conducted using consenting post-op coronary artery bypass graft (CABG) patients

who had temperatures less than 36°C on admission to the surgical ICU. Temperatures were recorded from the left and right tympanic membranes via the ITT, and from the PAC and RP, every 20 minutes until the temperature stabilized (Shinozaki et al., 1988).

The precision of the instruments was estimated from the standard deviation (SD) of the differences. A larger SD was reported in vivo for the RP than for the ITT (Student's t-test, $p < .05$). When all of the data were grouped, a correlation coefficient between the ITT and PAC was 0.98 (Shinozaki et al., 1988).

The reproducibility of the ITT was determined by comparing the left and right tympanic membrane temperatures. The difference between the two measurements ($0.0^{\circ} \pm 0.1^{\circ}C$) was not significant (Shinozaki et al., 1988).

The authors of the study concluded that the prototype of the ITT could accurately measure temperature in vitro over a clinical range of temperatures from 34.0° to 39.5°C, and could accurately assess core temperature in vivo. The instrument was also reported to be capable of reproducibility, as evidenced by the insignificant difference between left and right tympanic membrane temperatures (Shinozaki et

al., 1988).

This study provides useful information regarding the accuracy and reproducibility of the ITT as measured in vitro; however, it is limited to patients who underwent elective CABG surgery (sample size unknown). Therefore, the results can not be generalized. A second concern is that the study was conducted on a prototype instrument rather than the marketed version.

Ros (1989) evaluated the ITT (FirstTemp^{R}) in an outpatient clinical setting. The results reported are opposite of the findings reported by Erickson, 1990, Terndrup et al., 1989, and Shinozaki et al., 1988.

The purpose of the study was to determine the relationship between the infrared tympanic thermometer (ITT) and glass-mercury thermometers (GMT) in an outpatient clinical setting. The study was conducted in the emergency department at Loyola University Medical Center in Illinois during November and December 1988. Those eligible to participate in the study were all patients less than 18 years of age. The sample consisted of 102 patients, ranging in age from 3 weeks to 17 years, with a mean age of 5.4 years (Ros, 1989).

The patients were first seen by a nurse and their oral or rectal temperature was taken using the GMT held

in place for three to five minutes until the temperature stabilized. Immediately thereafter, the patient was evaluated by a physician who measured the tympanic membrane temperature with the ITT. Each physician received instructions on the use of the ITT prior to the beginning of the study. After temperature measurements with the ITT, all patients were examined by the physician for auditory canal patency and tympanic membrane appearance with an otoscope. If the patient was diagnosed with acute otitis media (AOM), tympanic membrane temperature was measured in both ears (Ros, 1989).

Forty-nine percent (n = 50) of the sample had rectal temperatures measured, while fifty-one percent (n = 52) of the sample had oral temperatures measured. Thirteen percent (n = 13) had tympanic membranes partially obstructed with cerumen, while eighty-seven percent (n = 89) had tympanic membranes that could be completely visualized. Eight percent (n = 8) were diagnosed with AOM (Ros, 1989).

The differences between the temperatures in both ears in those diagnosed with AOM ranged from + 0.4^{o} to - 1.2^{o}C. The mean difference between the ITT and the GMT measurements were reported to be significantly

different (r = .763).

The authors concluded that the ITT cannot be automatically substituted for the GMT in the outpatient setting. No conclusions were drawn concerning the impact of AOM or cerumen on the accuracy or precision of the ITT readings. This study is lacking inter-rater reliability of the data collectors, evidence of control for ingestion of hot or cold liquids prior to oral temperature measurement, and in vitro and biomedical instrument calibration. The sample was limited with respect to age, and thus, prevents generalizability (Ros, 1989).

RESEARCH: CONTACT. Indwelling contact-type tympanic membrane temperature probes have been used for decades by anesthesia and correlate well with other measures of core temperature (oral, rectal and esophageal). The contact-type probes are in direct contact with either the tympanic membrane or the external auditory canal. Since the early 1960s, there have been several articles promoting tympanic thermometry (Benzinger, 1969; Cooper, Cranston, & Snell, 1964; Webb, 1973; Wilson, Knapp, Traber, & Priano, 1971). Comparisons have been made to oral, rectal, and esophageal temperatures.

Cooper et al. (1964) investigated the temperature of the wall of the external auditory meatus. Temperatures were measured in the external ear, mouth, and rectum with thermistors (type G.23, Standard Telephone Co. Ltd.). Measurements were made in 18 subjects; four were febrile. The investigators induced changes of central temperature by (a) immersing an arm in a water bath at 44^{o} - 45^{o}C, (b) subcutaneous injection of hexamethonium tartrate 1 mg/kg, (c) infusion of saline at 43^{o} - 44^{o}C into various arteries and veins, and (d) induction of fever with intravenous injection of preparations of bacterial pyrogens.

During stable control periods, ear temperatures averaged 0.05^{o}C lower than sublingual temperature, SD $\pm$ 0.18^{o}C. In the experimental groups, the changes in ear and oral temperatures were correlated, $r = 0.915$, $p < 0.001$ (Cooper et al., 1964).

One portion of the study suggested that a change in ear temperature can be induced by altering the temperature of blood flowing to the meatus; this was done by infusing warm saline into one carotid artery. There was a greater rise in temperature in the ear wall on the side of the infusion than in the opposite ear wall (Cooper et al., 1964).

The results of this study suggest that ear temperature and sublingual temperature behave similarly during short periods of moderate body heating, and the ear temperature provides a good indication of temperature changes in arterial blood. Although rectal temperature was measured, no data was reported for this site (Cooper et al., 1964). The experiment appears to have been conducted with rigor, however, due to the ethical constraints in today's research protocol, replication is impossible.

Nadel and Horvath (1970) compared tympanic and rectal temperatures over a range of ambient temperatures ranging from 10^{o} - 44^{o}C. Simultaneous readings of tympanic, rectal, and mean skin temperature were recorded at three minute intervals on three subjects. They concluded that temperature at the tympanic membrane was related to ambient temperature and was consistently lower than rectal temperature in the cold, and higher than rectal temperature in the heat. The authors attributed this to a skin temperature component of the tympanic membrane. Rectal temperature was independent of ambient temperature. The findings do not support using the tympanic membrane as a site for temperature measurement; however, the study

is limited due to the small sample size (n = 3).

Studies by Benzinger (1969), Wilson et al. (1971), and Webb (1973) reported high correlations between tympanic membrane temperatures and esophageal temperatures. Benzinger's study (1969) used the esophageal temperature as the standard for core temperature and compared it to tympanic membrane temperature measurements in general surgery patients. The difference between the two measures was 0.2^{o}C.

Wilson et al. (1971) evaluated fifty-four burned patients between the ages of two and 14 years. Three thousand and twenty-four measurements were statistically analyzed for sensitivity to small changes in core temperature. The findings suggest that esophageal temperature is the most sensitive method of recording rapidly changing small increments of core temperature. The correlation between the tympanic and esophageal probes was positive; the correlation coefficient was not reported.

Webb (1973) measured body temperature by a tympanic membrane thermocouple in patients undergoing cardiopulmonary bypass (n = 35). Simultaneous measurements with the esophageal probe were recorded. The author reported a "close correlation" (p.731)

between the tympanic membrane and esophageal temperatures; however, correlation coefficients were not reported in the article. The average difference between the two recordings was 0.2°C; the largest recorded difference being 1°C in two instances.

Shiraki, Konda, and Sagawa (1986) evaluated tympanic and esophageal temperature responses to core blood temperature changes during hyperthermia. Tympanic, esophageal, rectal and core blood (pulmonary artery) temperatures were recorded in three patients during iatrogenic whole-body hyperthermia for the treatment of advanced malignant cancer. The findings reported suggest esophageal temperature reflects the temperature changes in the pulmonary artery more quickly than the tympanic temperature. "Tympanic temperature was consistently lower than the blood temperature of the heart during steady state" (p.98).

Shiraki et al. (1986) suggest "esophageal temperature as a preferable index of central blood temperature" (p. 98). The study is limited by the size and homogeneity of the sample.

ADVANTAGES AND DISADVANTAGES. The tympanic membrane site offers several advantages over conventional methods of temperature measurement: (a)

The speed with which the ITT measures temperature (within two seconds) can save nursing time; (b) there is a low potential for cross-contamination because the external auditory canal is a dry environment and the ITT uses disposable probe covers; (c) it is noninvasive and can be used on adults, children, and neonates in any patient setting; (d) it is unaffected by ingestion of cold and hot liquids and by smoking (Shinozaki et al., 1988; Terndrup et al., 1989); and (e) is highly acceptable to both patients and staff (Barber & Kilmon, 1989).

Most of the conventional temperature measuring devices have inherent problems with their use, and can only be used in certain circumstances or in specific patient care settings (Shinozaki et al., 1988). The pulmonary artery is the most representative site available for making "core" deep body temperature measurements (Bligh, 1973; Shellock & Rubin, 1982). However, the use of a pulmonary artery catheter is limited to the intensive care unit setting and poses some potential serious risks, such as catheter induced sepsis and pulmonary artery thrombosis (Shellock & Rubin, 1982).

Traditionally, rectal temperature has been widely

used for both the clinical and experimental measurement of core temperature (Bligh, 1973; Terndrup et al., 1989). However, there are several disadvantages when using the rectal site: (a) It requires more time because of time spent disrobing the patient and for providing privacy; (b) it is unpleasant for the patient and staff; (c) there are specific contraindications (e.g. neutropenia, rectal surgery, increased intracranial pressure, ischemic chest pain); and, (d) there is the potential for cross-contamination (Shinozaki et al., 1988; Terndrup et al., 1989).

Oral temperature measurement is frequently used because of convenience. However, ingestion of cold and hot liquids (Forster, Adler, & Davis, 1970; Terndrup et al., 1989; Woodman, Parry, & Simms, 1967), technique (Baker et al., 1984; Erickson, 1980), and time of probe placement (Baker et al., 1984) have been demonstrated to affect oral temperature.

The advantages of axillary temperature measurement are noninvasiveness and convenience (Terndrup et al., 1989). The review of the literature suggests that the accuracy of axillary temperature measurement has not been rigorously researched.

Summary. The conflicting results of the research studies reviewed indicate the need for further investigation. In addition, only one of the research studies reviewed, Shinozaki et al., 1988, contains information about the accuracy (validity) and precision (reliability) of the devices used in their study. In all other studies, where accuracy (validity) and precision (reliability) of the ITT had not been established prior data collection, the results must be interpreted with a degree of skepticism.

In addition, the statistics employed in each of the four studies are incomplete (Erickson, 1990; Ros, 1989; Shinozaki et al., 1988; Terndrup et al., 1989). All four reported correlation coefficients, none reported the residual differences among the various methods of temperature measurement for the in vitro or the in vivo protocols.

Correlations are used to answer the question, "to what extent are the variables related?" (LoBiondo-Wood & Haber, 1990, p. 304). The correlation coefficient r "allows us to state mathematically what relationship exists between two variables" (Munro, Visintainer, & Page, 1986, p.64). The relationship can be positive or negative. A positive relationship means that as one

variable increases, the other variable also increases. Whereas, a negative relationship means that as one variable increases, the other decreases.

It is possible to have a strong, positive relationship, and yet have a large residual difference between the two variables. Thus, it is important to determine and report residual differences, if correlation coefficients are computed, when determining accuracy (validity) and precision (reliability).

In vitro determination of accuracy (validity) and precision (reliability) is necessary before researching this device on human subjects. Further, empirical support of the ITT in vitro and in vivo is needed before adoption of this device in clinical practice.

The in vitro calibration of the ITT is an efficient means of establishing accuracy (validity) and precision (reliability). Establishing a standardized protocol and using a thermometer traceable to the National Bureau of Standards in a laboratory environment will allow control of measurement error.

CHAPTER III

Methodology

Design

The study design was an in vitro calibration. The instruments used in the study were: (a) The Fisher Scientific Isotemp Refrigerated Circulator Model 9000 (see Appendix G); (b) a glass mercury thermometer (GMT) traceable to the National Bureau of Standards (see Appendix B); (c) two FirstTemp^{R} Infrared Tympanic Thermometers (see Appendix E); and, (d) the Diatek oral probe (see Appendix C). Objectivity was enhanced by use of calibrated equipment, adherence to standardized protocols, and establishment of inter-observer reliability.

Setting

The study was conducted in the Clinical Investigations Facility at Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas. The facility is accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The AAALAC is the veterinary equivalent of the Joint Commission for the Accreditation of Hospitals, and is the national accrediting agency for laboratory animal care facilities in the United States.

Sample and Sampling Technique

The in vitro calibration was performed on the FirstTemp^{R} Infrared Tympanic Thermometer and the Diatek oral probe over a clinically useful temperature range of 34.0^{o} to 40.0^{o}C. Each instrument was sampled three times at each temperature, in 0.5^{o}C increments.

Ethical Considerations

The study was not performed on human or animal subjects.

Data Collection

The in vitro calibration was a three phase study. Phases I and II were performed once, and Phase III was performed twice.

Phase I - biomedical calibration. Biomedical calibration of the Fisher Scientific Isotemp Refrigerated Circulator Model 9000 was performed in April, 1990 (see Appendix G). The FirstTemp^{R} Infrared Tympanic Thermometers were received directly from FirstTemp^{R} Intelligent Medical Systems, presumably calibrated (see Appendix E). The Diatek oral probe was calibrated on July 25, 1990, by a certified technician, according to the instructions provided by the manufacturers and in accordance with the Clinical Investigations Facility at Wilford Hall Medical Center.

The residual difference between the Diatek oral probe and the Dekabox Decade Resistor DB 62 during biomedical calibration was + 0.1^{o} to + 0.2^{o}C (see Appendix C).

Phase II - in vitro environment temperature stability. Phase II was conducted by the primary investigator and the research assistant. The purposes of Phase II were to determine (a) in vitro environment temperature stability, (b) in vitro environment equilibration time, and (c) inter-observer reliability when reading the glass mercury thermometer.

1. The GMT was heated to 40.0^{o}C, the temperature of the highest test point, within one hour prior to beginning Phase II. This was recommended by the Ever Ready Thermometer Company (see Note H, Appendix B).

2. The Fisher Scientific Isotemp Refrigerated Circulator Model 9000 was connected to the in vitro environment.

3. The position of the GMT in the water bath was randomly determined with the toss of a fair coin.

4. The GMT was secured in the correct position with a rubber stopper.

5. The in vitro environment temperature was calibrated to 34.0^{o}C by adjusting dials on the Fisher Scientific Isotemp Refrigerated Circulator Model 9000.

6. The primary investigator and the research assistant independently recorded the Fisher Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature and the GMT temperature at "Time 0" on individual data collection sheets (see Appendix D). Time was kept with a digital stopwatch.

7. The primary investigator and the research assistant independently recorded the Fisher Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature and GMT temperature every minute for five minutes.

8. Steps 5 through 7 were repeated for 34.5°, 35.0°, 35.5°, 36.0°, 36.5°, 37.0°, 37.5°, 38.0°, 38.5°, 39.0°, 39.5°, and 40.0°C.

9. The maximum equilibration time across the entire temperature range (34.0° through 40.0°C) was determined and recorded. The maximum equilibration time was determined to be five minutes; the amount of time the in vitro environment required to stabilize and remain constant when increased in 0.5°C increments (see Appendix D).

Phase III - calibration of ITT A, ITT B and the Diatek oral probe. Phase III was conducted by the primary investigator and the research assistant. The

purposes of Phase III were to determine (a) the residual differences, or the difference between the ITT and the glass mercury thermometer, and the difference between the Diatek oral probe and the glass mercury thermometer, and (b) the reproducibility (consistency) of the ITT and the Diatek oral probe, across a clinically useful temperature range of 34.0° to 40.0°C, in 0.5°C increments.

The primary investigator and research assistant methodically practiced the written protocol prior to beginning Phase III. The primary investigator and research assistant were disciplined and strictly adhered to the written protocol throughout Phase III.

1. The GMT was heated to 40.0°C, the temperature of the highest test point, within one hour prior to beginning Phase III. This was recommended by the Ever Ready Thermometer Company (see Note H, Appendix B).

2. The positions of the GMT, ITT A and ITT B sensor probes, and the Diatek oral probe were randomly determined with the toss of a fair coin (see Appendix F).

3. The positions of the primary investigator and the research assistant were determined with the toss of a fair coin (Position #1 - Operate ITT A and ITT B; and

Position #2 - Head GMT temperature, Diatek oral probe display and Fisher Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature).

4. The in vitro environment temperature was calibrated to 34.0°C by adjusting dials on the Fisher Scientific Isotemp Refrigerated Circulator Model 9000.

5. The timer on the stopwatch was started. When the five minute maximum equilibration time from Phase II (In Vitro Environment Temperature Stability) was reached, ITT A and ITT B, and the Diatek oral probe were placed in the ports at the appropriate position (see Appendix F).

6. ITT A, ITT B, and the Diatek oral probe were activated simultaneously.

7. The GMT temperature, Diatek oral probe readout, Fisher Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature, and ITT A and ITT B readouts were read within two seconds of each other, and were recorded in degrees centigrade (see Appendix H).

8. Reading #2 - after one minute, steps 6 and 7 were repeated at the appropriate positions.

9. Reading #3 - after one minute, steps 6 and 7 were repeated at the appropriate positions.

10. ITT A, ITT B, and the Diatek oral probe were returned to their respective charger while the in vitro environment temperature was increased by 0.5°C and during the five minute in vitro environment equilibration time.

11. Steps 4 through 10 were repeated from 34.5° to 40.0°C in 0.5°C increments.

12. The water bath was cooled to 34.0°C.

13. ITT A, ITT B, and the Diatek oral probe were returned to their respective charger for 30 minutes.

14. After 30 minutes, steps 2 through 11 were repeated.

Data Analysis

This study concerned itself with the measurement of temperature in degrees Celsius. Temperature is interval level data when measured in Celsius (Polit & Hungler, 1987).

Inter-observer reliability (equivalence) was established by the primary investigator and a research assistant who were trained on the use of the ITT and used the written research protocol. Consistency between the researcher's readings was determined during Phase II (In Vitro Environment Temperature Stability) at 99% accuracy.

The accuracy of ITT A, ITT B, and the Diatek oral probe thermometers was determined by a comparison of the temperatures obtained with ITT A, ITT B, and the Diatek oral probe in an in vitro environment, against a glass mercury thermometer traceable to the National Bureau of Standards. The accuracy of the instruments (ITT A, ITT B, and Diatek oral probe) was estimated from the residuals of the differences in temperature (ITT A minus precision GMT; ITT B minus precision GMT; Diatek oral probe minus precision GMT). Scatter plots of the data were generated to analyze the consistency and bias of the data points across a clinically useful temperature range of 34.0° to 40.0°C.

Reproducibility was determined in an in vitro environment against a glass mercury thermometer traceable to the National Bureau of Standards and scaled to 0.1°C. The in vitro calibration for each device was done over a clinically useful temperature range of 34.0° to 40.0°C. Each device was tested three times at each temperature, in 0.5°C increments. Phase III was performed twice.

CHAPTER IV

Results

Overview

This chapter will discuss the results found during the in vitro calibration of the FirstTemp^{R} Infrared Tympanic Thermometer. The purpose of the study was to determine the accuracy (validity) and precision (reliability) of the FirstTemp^{R} Infrared Tympanic Thermometer when compared to a glass mercury thermometer traceable to the National Bureau of Standards in vitro.

The in vitro calibration was a three phase study. Phase I was the biomedical calibration of the equipment used in the study. During Phase II, the primary investigator and the research assistant determined the in vitro environment temperature stability, the in vitro environment equilibration time, and inter-observer reliability when reading the glass mercury thermometer. And during Phase III, the primary investigator and the research assistant determined the residual differences between the ITT and the glass mercury thermometer, and the Diatek oral probe and the glass mercury thermometer, across a clinically useful temperature range of 34.0^{o} to 40.0^{o}C, in 0.5^{o}C

increments. Phases I and II were conducted once; phase III was conducted twice.

Inter-observer Reliability

The maximum inter-observer difference (see Table 1) for each observation time, across all temperature increments, was $\pm$ 0.10^{o}C (r = .99). The raw data used to calculate inter-observer reliability is presented in Appendix D.

Table 1

Phase II Inter-observer Differences: Determination of Water Bath Temperature Stability

Difference*	Observations	Percentage
+ 0.10	8	10%
0.00	68	87%
- 0.10	2	3%

* Difference = Primary investigator's reading minus the research assistant's reading.

Research Questions

Research question #1. What is the accuracy (validity) of the FirstTemp^{R} ITT and the Diatek oral probe, when compared with a glass mercury thermometer (National Bureau of Standards), tested in an in vitro environment across a temperature range of 34.0^{o} - 40.0^{o}C ?

The in vitro accuracy (validity) of ITT A, ITT B, and the Diatek oral probe thermometers was determined by a comparison of the temperatures obtained with ITT A, ITT B, and the Diatek oral probe in an in vitro environment, against a glass mercury thermometer traceable to the National Bureau of Standards during Phase III.

The in vitro environment temperature was calibrated to 34.0^{o}C by adjusting dials on the Fisher Scientific Isotemp Refrigerated Circulator Model 9000. When the five minute maximum equilibration time from Phase II (In Vitro Environment Temperature Stability) was reached, ITT A and ITT B, and the Diatek oral probe were placed in the ports at the appropriate position (see Appendix F). ITT A, ITT B, and the Diatek oral probe were activated simultaneously. The **absolute** GMT temperature, Diatek oral probe readout, Fisher

Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature, and ITT A and ITT B readouts were recorded in degrees centigrade. Each device was tested three times within a three minute time period. The procedure was repeated for each temperature, from 34.0° through 40.0°C, in 0.5° increments (see Protocol 1, Appendix H). After 30 minutes, the entire protocol was repeated (see Protocol 2, Appendix H). There are 39 data points for each instrument, in each protocol.

The accuracy (validity) of the instruments (ITT A, ITT B, and Diatek oral probe) was estimated from the residuals of the differences in temperature (ITT A minus precision GMT; ITT B minus precision GMT; Diatek oral probe minus precision GMT). Scatter plots of the data were generated to analyze the consistency and bias of the data points across a temperature range of 34.0° to 40.0°C (see Figures 2 through 7, pp. 59-64). The raw data used to calculate the accuracy (validity) and to generate the scatter plots is presented in Appendix H.

Figures 2 through 7 graphically illustrate the residual differences in temperature between each device tested and the precision GMT: (a) Figure 2 represents the residual differences between ITT A and the

precision GMT from Protocol 1; (b) figure 3 represents the residual differences between ITT A and the precision GMT from Protocol 2; (c) figure 4 represents the residual differences between ITT B and the precision GMT from Protocol 1; (d) figure 5 represents the residual differences between ITT B and the precision GMT from Protocol 2; (e) figure 6 represents the residual differences between the Diatek oral probe and the precision GMT from Protocol 1; and (f) figure 7 represents the residual differences between the Diatek oral probe and the precision GMT from Protocol 2.

In Figures 2 through 7, the horizontal line represents the precision glass mercury thermometer reading from 34.0° through 40.0°C. The vertical line represents the residual difference between each instrument and the glass mercury thermometer: ITT A minus precision GMT; ITT B minus precision GMT; Diatek oral probe minus precision GMT.

Each data point from Appendix H is plotted with respect to the **absolute** precision glass mercury thermometer reading. For example, if the ITT A digital readout was 34.4°C and the glass mercury thermometer reading was 34.1°C, the data point was plotted at the intersection of 34.1°C on the horizontal line, and 0.3

(34.4^{o} - 34.1^{o} = 0.3) on the vertical line.

Table 2 displays the range of the residual differences between ITT A and the glass mercury thermometer, ITT B and the glass mercury thermometer, and the Diatek oral probe and the glass mercury thermometer, across the entire temperature range of 34.0^{o} to 40.0^{o}C. The residual range is listed from low to high residual difference, and is based on all 39 data points for each instrument.

The accuracy specification set by the FirstTemp^{R} ITT manufacturer is $\pm$ 0.2^{o}F ($\pm$ 0.1^{o}C) from 96^{o}F - 102^{o}F (35.5^{o}C - 38.9^{o}C). Table 3 displays the range of the residual differences between ITT A and the glass mercury thermometer, and ITT B and the glass mercury thermometer in the accuracy range specified by the FirstTemp^{R} manufacturer. The residual range is based on 21 data points in the range of 35.5^{o} to 38.5^{o}C.

Table 2

Phase III: Residual Differences from 34.0° - 40.0°C

Instrument	Protocol	Residual Range[1]	Mean[2]
ITT A	1	+ 0.3 to + 0.9	.51
ITT A	2	+ 0.1 to + 0.7	.42
ITT B	1	- 0.4 to + 0.3	.02
ITT B	2	- 0.3 to + 0.2	.01
Diatek oral	1	+ 0.1 to + 0.2	.14
Diatek oral	2	+ 0.1 to + 0.2	.17

Residual Range[1] = Low to high residual difference between the instrument (ITT A, ITT B, and Diatek oral probe) and the glass mercury thermometer, across the entire temperature range of 34.0° to 40.0°C. The residual range is based on all 39 data points for each instrument.

Mean[2] = The average residual difference across the entire temperature range of 34.0° to 40.0°C. The mean residual is based on all 39 data points.

Table 3

Phase III: Residual Differences from 35.5° - 38.5°C

Instrument	Protocol	Residual Range[1]	Mean[2]
ITT A	1	+ 0.3 to + 0.9	.53
ITT A	2	+ 0.2 to + 0.6	.42
ITT B	1	- 0.3 to + 0.2	0.0
ITT B	2	- 0.1 to + 0.2	0.0

Residual Range[1] = Low to high residual difference between the instrument (ITT A and ITT B) and the glass mercury thermometer, across the temperature range of 35.5°C to 38.5°C.

Mean[2] = The average residual difference across the temperature range of 35.5° to 38.5°C. The mean residual is based on 21 data points.

Research question #2. What is the reproducibility of the FirstTemp^{R} ITT and the Diatek oral probe as measured in an in vitro environment across a temperature range of 34.0^{o} - 40.0^{o}C?

Reproducibility (consistency), is the ability to produce the same results with repeated testing at the same temperature. Reproducibility was determined in an in vitro environment. The in vitro environment temperature was monitored with a precision glass mercury thermometer traceable to the National Bureau of Standards and scaled to 0.1^{o}C.

The in vitro environment temperature was calibrated to 34.0^{o}C by adjusting dials on the Fisher Scientific Isotemp Refrigerated Circulator Model 9000. When the five minute maximum equilibration time from Phase II (In Vitro Environment Temperature Stability) was reached, ITT A and ITT B, and the Diatek oral probe were placed in the in vitro environment ports at the appropriate position (see Appendix F). ITT A, ITT B, and the Diatek oral probe were activated simultaneously. The **absolute** GMT temperature, Diatek oral probe readout, Fisher Scientific Isotemp Refrigerated Circulator Model 9000 LCD temperature, and ITT A and ITT B readouts were recorded in degrees

centigrade. Each device was tested three times within a three minute time period. The procedure was repeated for each temperature, from 34.0^{o} through 40.0^{o}C, in 0.5^{o} increments (see Protocol 1, Appendix H). After 30 minutes, the entire protocol was repeated (see Protocol 2, Appendix H).

For each **absolute** temperature from 34.0^{o} through 40.0^{o}C, there were three residual differences: residual 1, residual 2, and residual 3. Scatter plots of the data were generated to analyze the consistency of the residual differences across the entire temperature range. Figures 2 through 7 graphically illustrate the three residual differences at each temperature increment. Tables 4 and 5 summarize Figures 2 through 7. The raw data used to analyze the reproducibility (consistency) and to generate the scatter plots is presented in Appendix H.

Table 4

Reproducibility (consistency) of the ITT and the Diatek Oral Probe from 34.0° to 40.0°C

Instrument	Protocol	Least[1]	Greatest[2]
ITT A	1	0.0°	0.3°
ITT A	2	0.0°	0.3°
ITT B	1	0.0°	0.5°
ITT B	2	0.0°	0.3°
Diatek oral	1	0.0°	0.1°
Diatek oral	2	0.0°	0.1°

Least[1] = The smallest difference among Residual 1, Residual 2, and Residual 3 at each temperature increment, across the entire temperature range of 34.0° to 40.0°C.

Greatest[2] = The largest difference among Residual 1, Residual 2, and Residual 3 at each temperature increment, across the entire temperature range of 34.0° to 40.0°C.

Table 5

Reproducibility (consistency) of ITT A and ITT B from 35.5° to 38.5°C

Instrument	Protocol	Least[1]	Greatest[2]
ITT A	1	0.0°	0.3°
ITT A	2	0.0°	0.3°
ITT B	1	0.0°	0.3°
ITT B	2	0.0°	0.3°

Least[1] = The smallest difference among Residual 1, Residual 2, and Residual 3 at each temperature increment, across the temperature range of 35.5° to 38.5°C.

Greatest[2] = The largest difference among Residual 1, Residual 2, and Residual 3 at each temperature increment, across the temperature range of 35.5° to 38.5°C.

FIGURE 2

Infrared Tympanic Thermometer A - Protocol 1

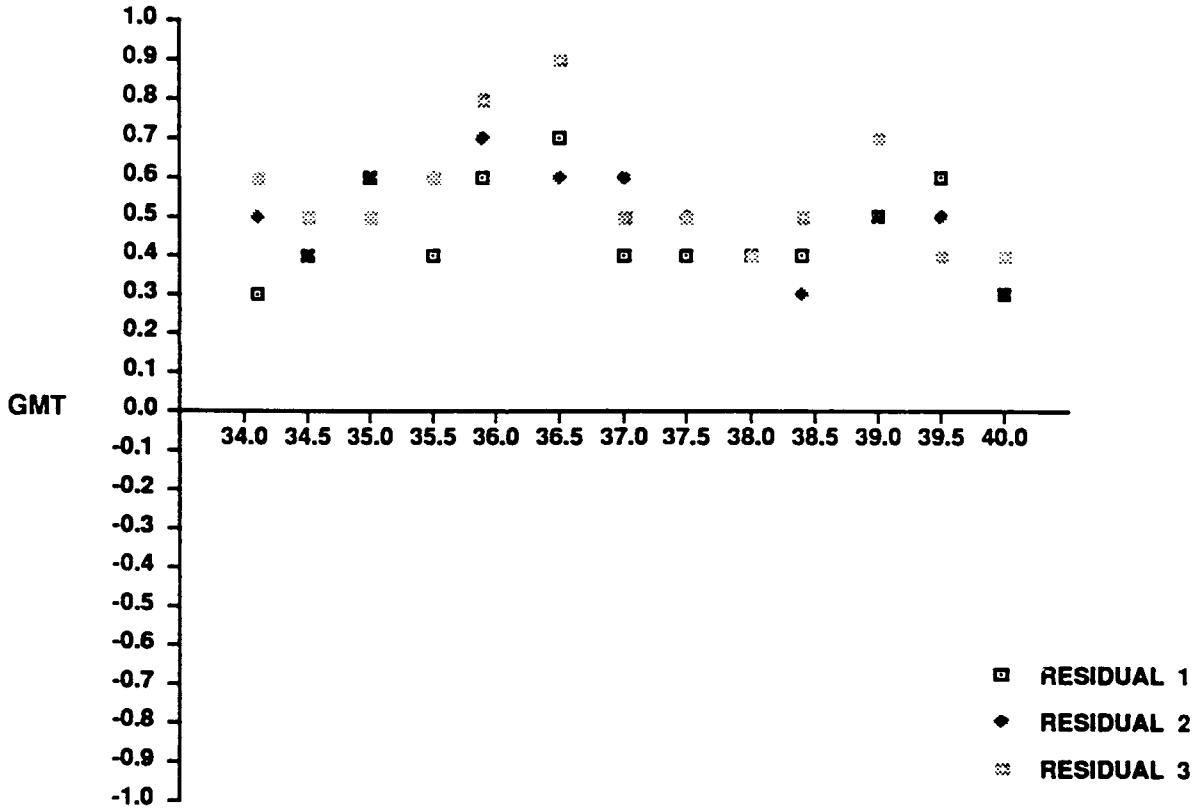


FIGURE 3

Infrared Tympanic Thermometer A - Protocol 2

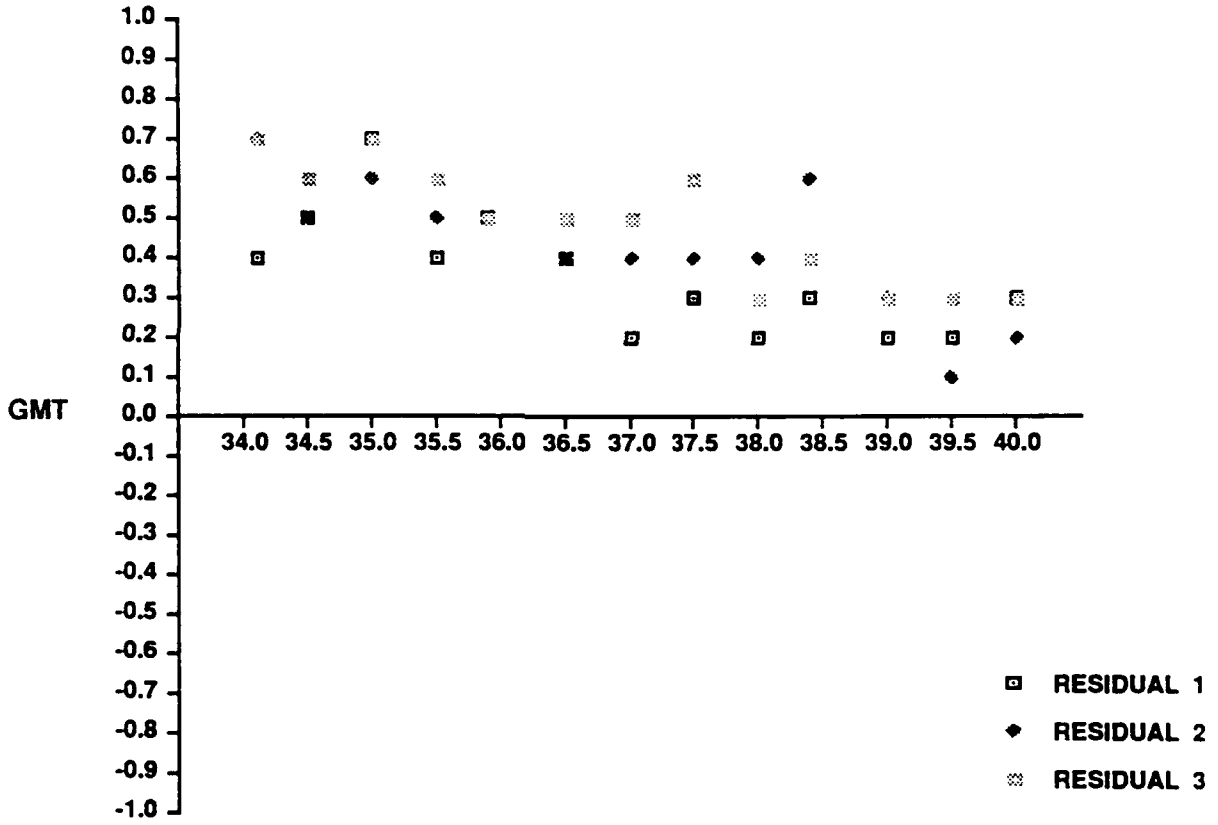


FIGURE 4

Infrared Tympanic Thermometer B - Protocol 1

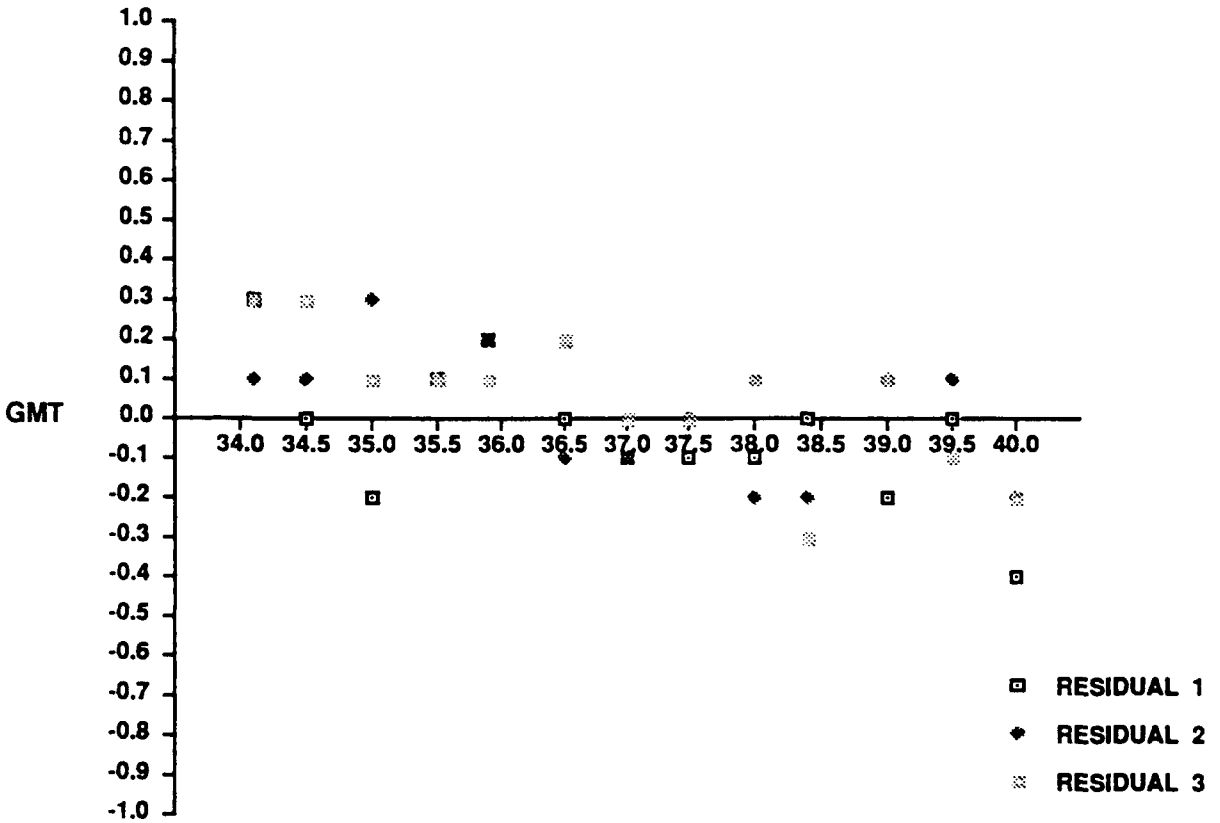


FIGURE 5

Infrared Tympanic Thermometer B - Protocol 2

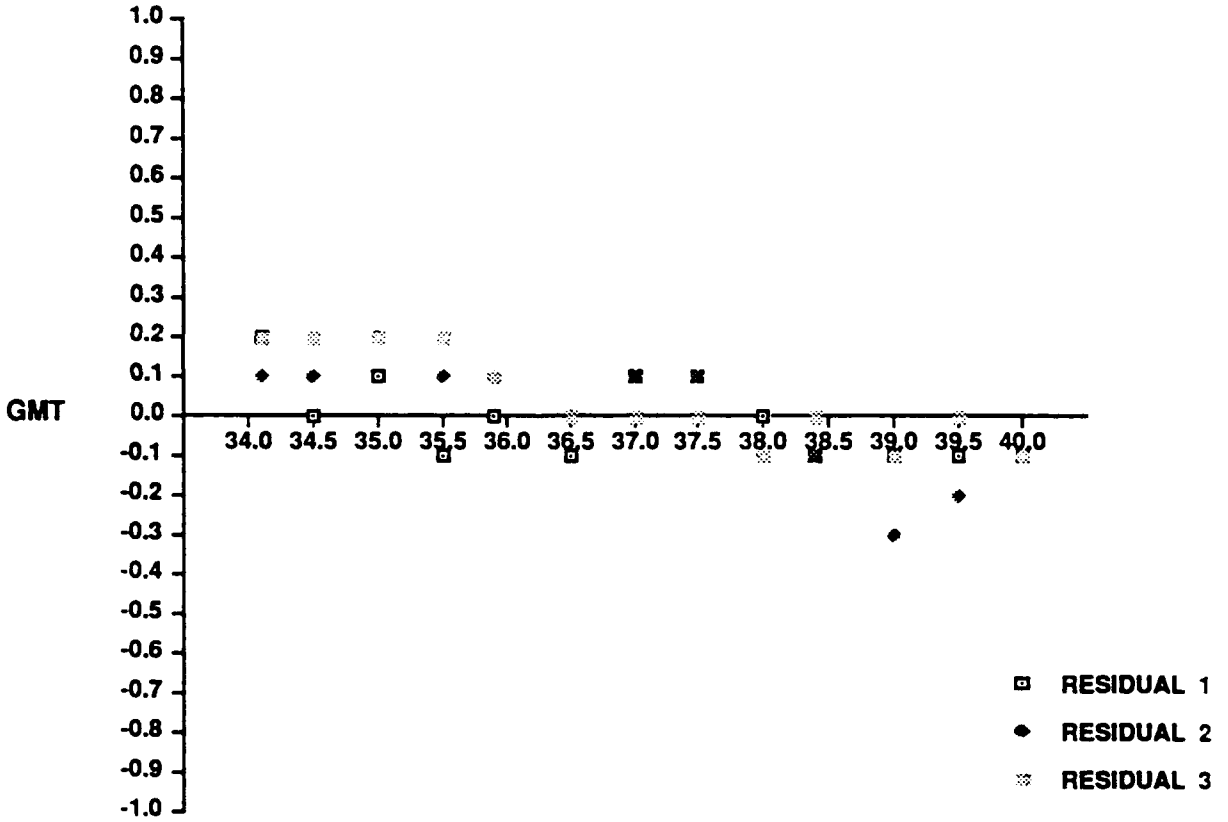


FIGURE 6

Diatek Oral Probe - Protocol 1

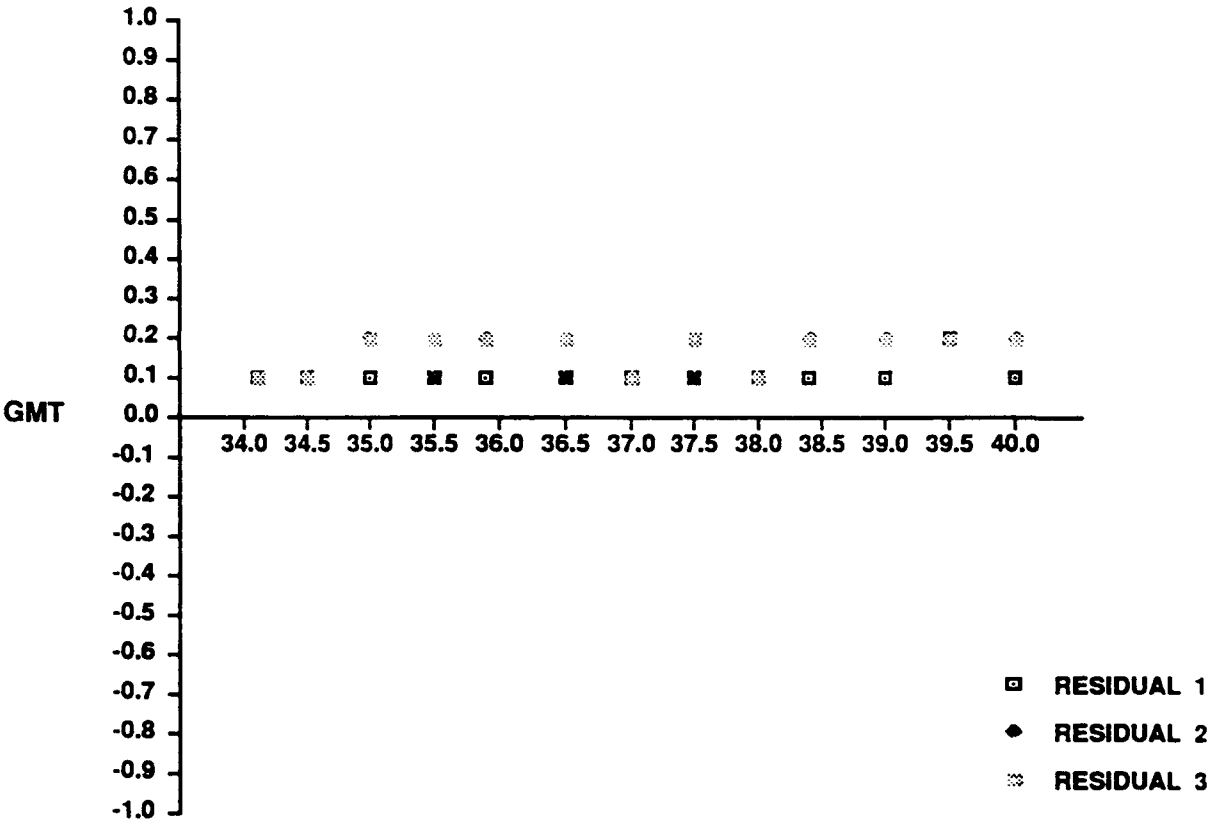
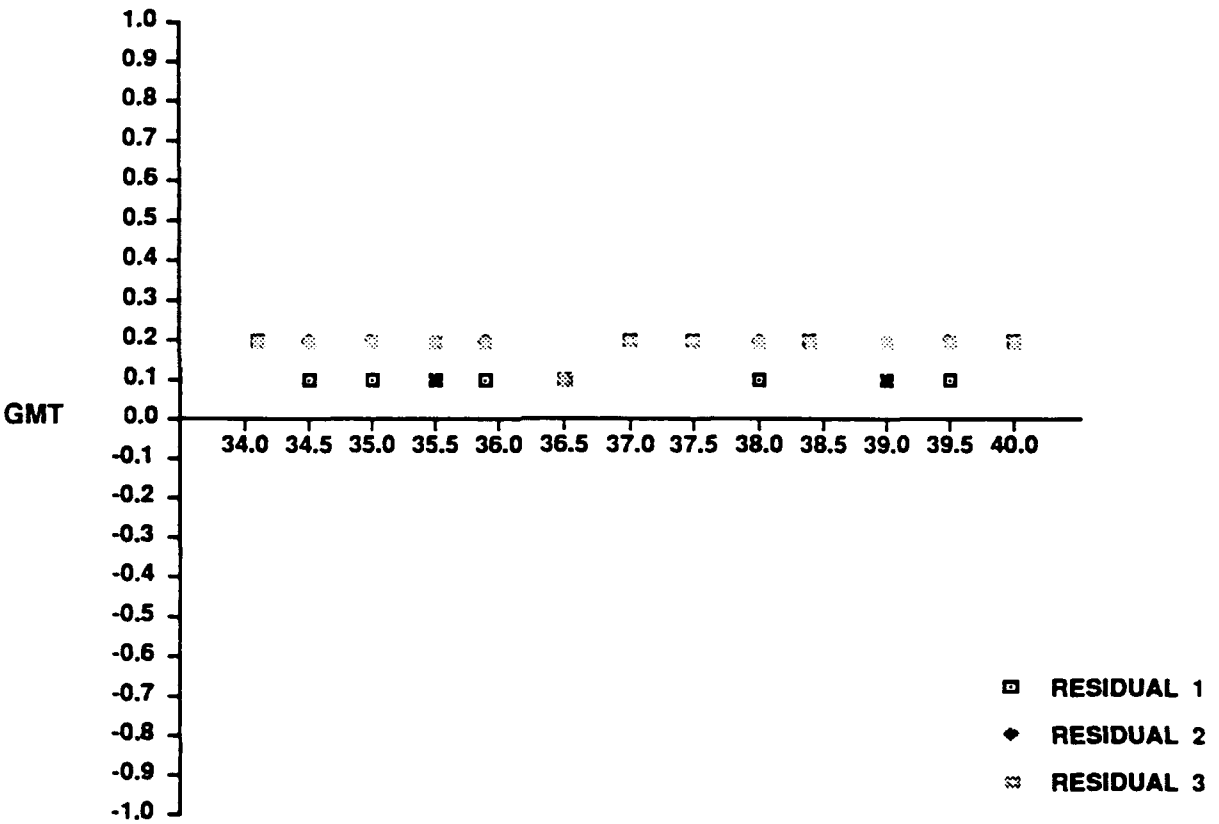


FIGURE 7

Diatek Oral Probe - Protocol 2



CHAPTER V

Summary and Discussion

Summary

An in vitro calibration was conducted to determine the accuracy (validity) and precision (reliability) of the FirstTemp^{R} Infrared Tympanic Thermometer when compared to a glass mercury thermometer traceable to the National Bureau of Standards. The in vitro calibration was a three phase study.

Phase I was the biomedical calibration of the equipment used in the study. During Phase II, the primary investigator and the research assistant determined the in vitro environment temperature stability, the in vitro environment equilibration time, and inter-observer reliability when reading the glass mercury thermometer. And during Phase III, the primary investigator and the research assistant determined the residual differences between the ITT and the glass mercury thermometer, and the Diatek oral probe and the glass mercury thermometer, across a clinically useful temperature range of 34.0^{o} to 40.0^{o}C, in 0.5^{o} increments. Phases I and II were conducted once; Phase III was conducted twice.

The maximum inter-observer difference (see Chapter

IV, Table 1) for each observation time, across all temperature increments, was $\pm$ 0.10°C (r = .99). The accuracy of the instruments was estimated from the residuals of the differences in temperature (ITT A minus precision GMT; ITT B minus precision GMT; Diatek oral probe minus precision GMT). The residual differences calculated encompassed two temperature ranges. The first temperature range, 35.5° to 38.5°C, was within the manufacturer claim of precision tolerance, $\pm$ 0.1°C. The second temperature range, 34.0° to 40.0°C, is a clinically useful range.

Within the temperature range of 35.5° to 38.5°C, across all protocols, the residual difference range for ITT A and B was + 0.2 to + 0.9, and - 0.3 to + 0.2, respectively. Within the temperature range of 34.0° to 40°C, across all protocols, the residual difference range for ITT A, ITT B, and the Diatek oral probe was as follows: (a) ITT A, + 0.1 to + 0.9; (b) ITT B, - 0.4 to + 0.3; and, (c) Diatek oral probe, + 0.1 to + 0.2 (see Chapter IV, Tables 2 and 3, and Figures 2 through 7).

The reproducibility of ITT A and ITT B, across all protocols, within the temperature range of 35.5° to 38.5°C, was 0.0° to 0.3°C. The reproducibility of ITT

A, across all protocols, within the temperature range of 34.0° to 40.0°C, was 0.0° to 0.3°C; ITT B was 0.0° to 0.5°C. The reproducibility of the Diatek oral probe across the entire temperature range of 34.0° to 40.0°C was 0.0° to 0.1°C (see Chapter IV, Figures 2 through 7 and Tables 4 and 5).

Discussion

The in vitro calibration method in this study demonstrated the feasibility of using an air-tight continuously circulating water bath to determine the accuracy (validity) and precision (reliability) of electronic equipment used to measure temperature. This study examined: (a) the residual differences between the ITT and the precision GMT, and the Diatek oral probe and the precision GMT; and (b) the reproducibility (consistency) of each instrument, at each temperature interval.

ITT A. The precision tolerance set by the ITT manufacturers was ± 0.1°C, within the temperature range of 35.5° to 38.5°C. Within this temperature range, the residual differences ranged from + 0.3 to + 0.9, with a mean of .53 during Protocol 1, and + 0.2 to + 0.6, with a mean of .42 during Protocol 2. None of the 21 data points (0%) were within the ± 0.1°C precision tolerance

set by the manufacturer during Protocol 1 and 2.

The temperature range which is considered clinically useful is 34.0° to 40.0°C. Within this temperature range, the residual differences ranged from + 0.3 to + 0.9, with a mean of .51 during Protocol 1, and + 0.1 to + 0.7, with a mean of .42 during Protocol 2.

ITT A was imprecise, as demonstrated by its large residual differences, and biased, as demonstrated by readings that were consistently higher than the precision glass mercury thermometer. This occurred across the entire temperature range of 34.0° to 40.0°C. ITT A did not meet the accuracy specifications set by the manufacturer.

ITT B. The precision tolerance set by the ITT manufacturers was ± 0.1°C, within the temperature range of 35.5° to 38.5°C. Within this temperature range, the residual differences ranged from - 0.3 to + 0.2, with a mean of 0.0 for Protocol 1, and - 0.1 to + 0.2, with a mean of 0.0 for Protocol 2. Fifteen of the 21 data points (71%) during Protocol 1, and 20 of the 21 data points (95%) during Protocol 2, were within the ± 0.1°C precision tolerance set by the manufacturer.

The temperature range which is considered

clinically useful is 34.0° to 40.0°C. Within this temperature range, the residual differences ranged from - 0.4 to + 0.3, with a mean of .02 during Protocol 1, and - 0.3 to + 0.2, with a mean of .01 during Protocol 2.

At the low end of the temperature range (34.0° to 36.0°C), across all protocols, the ITT B readings were higher than the precision glass mercury thermometer. At the high end of the temperature range (38.5° to 40.0°C), across all protocols, the ITT B readings were lower than the precision glass mercury thermometer.

ITT B was precise within the temperature range of 35.5° to 38.5°C. Precision was demonstrated by 71% of the data points in Protocol 1, and 95% of the data points in Protocol 2, falling within $\pm$ 0.1°C of the precision glass mercury thermometer, with a mean residual difference of 0.0°C. ITT B was unbiased, as demonstrated by readings that were higher than the precision glass mercury thermometer at the low end of the temperature range, and lower than the precision glass mercury thermometer at the high end of the temperature range. ITT B met the accuracy specifications set by the manufacturer.

Diatek oral probe. The residual differences across the entire temperature range of 34.0° to 40.C°C for the Diatek oral probe was + 0.1 to + 0.2, with a mean of .14 during Protocol 1, and + 0.1 to + 0.2, with a mean of .17 during Protocol 2. Twenty-three of the 39 data points (59%) from Protocol 1, and 12 of the 39 data points (31%) from Protocol 2 were + 0.1°C higher than the precision glass mercury thermometer. Thirty-nine of the 39 data points (100%) from both Protocols 1 and 2, across the entire temperature range of 34.0°C to 40.0°C, were within + 0.2°C of the precision glass mercury thermometer.

The Diatek oral probe was precise. Precision was demonstrated by 100% of the data points falling within + 0.2°C of the precision glass mercury thermometer. The Diatek oral probe had a stable bias, as demonstrated by readings that were consistently higher than the precision glass mercury thermometer by 0.1° to 0.2°C, across the entire temperature range of 34.0° to 40.0°C.

Although much has been written concerning tympanic membrane temperatures, there were only four research studies reported in the literature specifically concerned with the ITT (Erickson, 1990; Ros, 1989;

Shinozaki, Deane, & Perkins, 1988; Terndrup, Allegra, & Kealy, 1989). The scope of these four studies were limited and the results conflicting. Only one study (Shinozaki et al., 1988) conducted an in vitro evaluation of the ITT.

Three of the four research studies suggested that the ITT can accurately measure temperature (Erickson, 1990; Shinozaki et al., 1988; Terndrup et al., 1989). Whereas one study (Ros, 1989) suggested that the ITT was not accurate ($r = .763$).

Three of the four studies were done in vivo (Erickson, 1990; Ros, 1989; Terndrup et al., 1989) without evidence of biomedical calibration of the instruments. Shinozaki et al. (1988) did both an in vitro and an in vivo analysis of the accuracy of the ITT.

The statistics employed in each of the four studies were incomplete. All four reported correlation coefficients (Erickson, 1990; Ros, 1989; Shinozaki et al., 1988; Terndrup et al., 1989). Shinozaki et al. (1988) reported standard deviations, as well as correlation coefficients. None of the four reported the residual differences between the devices used in their studies.

This study determining the in vitro accuracy (validity) and precision (reliability) of the FirstTemp^{R} Infrared Tympanic Thermometer when compared to a glass mercury thermometer, is difficult to compare with the results of the other studies. It is the first to use an artificial auditory canal in an in vitro environment. Additionally, this study is the first to report residual differences among the various methods of temperature measurement, and to report simultaneous testing of more than one ITT.

The in vitro calibration demonstrated: (a) ITT A was imprecise, had an inconsistent bias, and did not meet the accuracy specifications set by the manufacturer; (b) ITT B was precise within the temperature range of 35.5^{o} to 38.5^{o}, was unbiased, and met the accuracy specifications set by the manufacturer; and, (c) the Diatek oral probe was precise and consistently biased. See Chapter IV, Tables 2 through 5 and Figures 2 through 7, and Appendix H for individual results.

One possible explanation for the large difference between ITT A and ITT B is an instrumentation sensitivity issue that warrants further investigation. It is assumed that Intelligent Medical Systems, the ITT

manufacturer, calibrated the devices prior to shipment. However, the ITT may be an extremely sensitive instrument that requires recalibration after shipping.

Application to Nursing Practice

Temperature measurement is one of the physiologic events which has implications for treatment protocols. In light of the prevalence of monitoring temperature in all clinical settings, it is imperative that nurses rigorously test the accuracy (validity) and the precision (reliability) of all devices used for temperature measurement. Testing the manufacturer specification claims for each instrument, and establishing accuracy and precision of these instruments, are mandatory prior to adopting their use in clinical practice.

There are several concerns that need to be addressed before using the ITT in the clinical setting. First, calibration of the ITT needs attention. If ITT A and ITT B were calibrated prior to shipment, why was there such a large incongruity between their residual differences (see Chapter IV, Figures 2 through 5)? And, is the ITT so sensitive, that shipment can alter the calibration? Is the ITT so sensitive that the calibration is altered when carried around by the nurse

in clinical settings?

The large difference between ITT A and ITT B could have critical implications in the clinical setting. The residual difference, in the clinical temperature range of 34.0° to 40.0°C, for ITT A (Protocol 1 and 2) was + 0.1° to + 0.9°C, and - 0.4° to + 0.3°C for ITT B (Protocol 1 and 2). If for example, the nurse used ITT A for monitoring a patient's temperature, and the reading was + 0.9°C higher than the actual temperature (the high extreme), and later used ITT B for a repeat temperature, and the reading was - 0.4°C lower than the actual temperature (the low extreme), the patient's actual temperature is in question. As a result, the underlying condition may not be diagnosed or treated.

A second concern deals with instrument bias. The Diatek oral probe was precise and had a constant bias of + 0.1° to + 0.2°C. When the instrument was calibrated prior to data collection, the primary investigator was told that it was + 0.1° to + 0.2°C high (see Appendix C). This type of bias is easy to account for because the nurse can subtract 0.1° to 0.2°C from the Diatek reading.

ITT A was also biased, with readings consistently higher than the glass mercury thermometer. However,

the bias is difficult to account for because the difference between ITT A and the glass mercury thermometer was inconsistent (+ 0.1^{o} to + 0.9^{o}C).

ITT B was precise within the manufacturer claim of precision tolerance, $\pm$ 0.1^{o}C, in the temperature range of 35.5^{o} to 38.5^{o}C. However, ITT B was unbiased as demonstrated by readings that were higher than the glass mercury thermometer at the low end of the temperature range, and lower than the glass mercury thermometer at the high end of the temperature range. This could result in readings that are higher than the actual temperature in hypothermic patients, and lower than the actual temperature in hyperthermic patients.

And lastly, the temperature range of 35.5^{o} to 38.5^{o}C (96.0^{o}F - 102^{o}F), the accuracy specification range set by the FirstTemp^{R} manufacturers, is of little clinical use in many clinical settings. Many patients in the Post Anesthesia Care Unit (PACU) are classified as hypothermic, with temperatures below 36.0^{o}C. Accurate temperature measurement in these patients may mean the difference between adequate rewarming after surgery and a lengthened stay with potential complications due to prolonged hypothermia.

Pediatric patients and patients who are septic

often present with temperatures much higher than 38.5°C. Furthermore, many clinical syndromes and diseases, such as acute leukemia, pneumococcal pneumonia, hepatitis, meningitis, tuberculosis, toxic shock syndrome, and otitis media are first manifested, or accompanied by an elevated temperature. Erroneous temperature readings in these patients may result in inadequate physical examinations and diagnostic testing, and inappropriate treatment.

Recommendations for Future Research

Is the FirstTemp^{R} Infrared Tympanic Thermometer (ITT) an accurate (valid) and precise (reliable) temperature measuring device? What is the reproducibility of the FirstTemp^{R} Infrared Tympanic Thermometer? Is the in vitro environment using an artificial auditory canal an appropriate method for determining ITT accuracy and precision? The answers to these questions remain inconclusive. This is the first study to use an artificial auditory canal in an in vitro environment, to report residual differences between instruments, and to report simultaneous testing of more than one ITT.

This in vitro study needs to be replicated using calibrated equipment and a standardized protocol. It

is recommended that more than two ITTs be simultaneously tested, and each instrument be tested four or five times at each temperature increment instead of three times. Increased replication at each temperature increment will strengthen the ability to determine the instrument's reproducibility. All up-dated versions of the ITT must also be vigorously tested in the same manner.

If the ITT is precise, accurate, and capable of reproducibility in subsequent in vitro studies, then it should be further examined in vivo. Recommendations for in vivo studies include: (a) use of calibrated equipment and a standardized protocol; (b) evidence of inter-rater reliability; (c) statistical analysis to include residual differences among the instruments used; (d) bilateral tympanic membrane derived temperature measurement with the ITT; and (e) a large, heterogeneous sample.

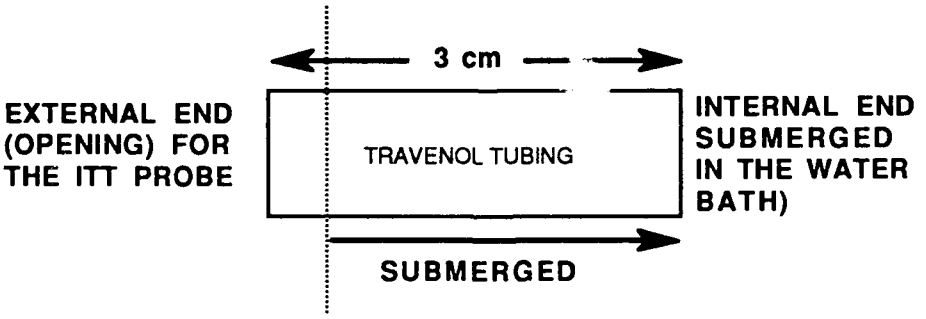
APPENDIX A

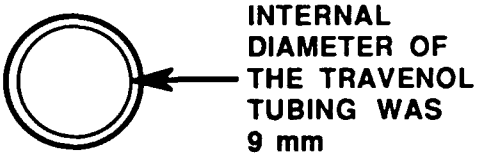
Artificial Auditory Canal

ARTIFICIAL AUDITORY CANAL

A dry, airtight "canal" made of Travenol plastic tubing. The inside diameter of the tubing was 9mm, the approximate diameter of the adult tympanic membrane (Ballenger, 1985; Bordley, Brookhouser, & Tucker, 1986; Williams, Warwick, Dyson, & Bannister, 1989). The tubing length was 3cm, the approximate length of the external auditory canal (Ballenger, 1985; Bordley et al., 1986; Williams et al., 1989).

The internal end of the plastic tubing (9mm) was in contact with the water bath and was sealed with a surgeon's glove stretched thinly over the end. The external end of the tubing was open. The ITT probe sealed the external opening of the artificial auditory canal.





APPENDIX B

Glass Mercury Thermometer Laboratory Test Certificate

EVER READY THERMOMETER CO., New York, N.Y. 10157

ITS-90

LABORATORY TEST CERTIFICATE

Liquid-in-Glass Thermometer

Marked – ERTCO

Instrument No. 2555

Thermometer Scale Range 25 *to* 55°C *in* 0.1 *divisions*
With Auxiliary Scale at 0°C

Tested for

ERTCO

RESULTS OF TEST

Thermometer Reading	Correction
-0.06°C	+0.06°C
25.00	.00
35.00	+ .06
45.00	.00
55.00	.00

If the correction is preceded by a + sign, it should be added to the thermometer reading; if it is preceded by a – sign, it should be subtracted from the thermometer reading to obtain the temperature. To use the corrections properly, reference should be made to the notes on the reverse side of this sheet.

Test No. 140220

Date 4/23/90

EVER READY THERMOMETER CO.

Certified by Shirley Vinderbaum

NOTES

** NOTE A.—The tabulated corrections apply for the condition of total immersion of the bulb and liquid column.

NOTE B.—The tabulated corrections apply for the condition of total immersion of the bulb and liquid column. Although this thermometer is not ordinarily used in this way, no significant errors should be introduced by neglecting the corrections for emergent stem and accordingly no stem correction sheet is attached.

NOTE C.—The thermometer was tested in a large, closed-top, electrically heated, liquid bath, being "immersed" . The temperature of the room was about 25° C (77° F). If the thermometer is used under conditions which would cause the average temperature of the emergent liquid column to differ markedly from that prevailing in the test, appreciable differences in the indications of the thermometer would result.

NOTE D.—The tabulated corrections apply provided the ice-point reading is . If the ice-point reading is found to be higher (or lower) than stated, all other readings will be higher (or lower) to the same extent.

** NOTE E.—The tabulated corrections apply provided the ice-point reading, taken after exposure for not less than 3 days to a temperature of about 20° C (70° F) is −0.06°C . If the ice-point reading is found to be higher (or lower) than stated, all other readings will be higher (or lower) to the same extent. If the thermometer is used at a given temperature shortly after being heated to a higher temperature, an error of 0.01° or less, for each 10° difference between the two temperatures, may be introduced. The tabulated corrections apply if the thermometer is used in its upright position; if used in a horizontal position, the indications may be a few hundredths of a degree higher.

NOTE F.—The tabulated corrections apply provided the reading when the thermometer is immersed in steam at 100° C (212° F) is . If the reading is found to be higher (or lower) than stated, all other readings will be higher (or lower) to the same extent. The temperature of steam is 100° C (212° F) only if the pressure is 760 mm (29.921 inches). If the pressure differs from 760 mm (29.921 inches) allowance must be made for this. If the pressure is higher (or lower) than 760 mm (29.921 inches) the temperature will be higher (or lower) than 100° C (212° F) by approximately 0.037° C per mm difference (1.68° F per inch difference).

NOTE G.—The tabulated corrections apply provided the reading when the thermometer is immersed in a bath at is . If the reading at this reference point is higher (or lower) than stated, all other readings will be higher (or lower) to the same extent.

NOTE H.—The thermometer, before testing, was heated to the temperature of the highest test point. The application of the tabular corrections to the readings of the thermometer will give true temperature differences, provided the thermometer is used in its upright position, and is heated previously (within an hour before using) to the highest temperature to be measured.

NOTE I.—The thermometer was tested for use in differential measurements, such as the measurement of temperature differences in a flow calorimeter. The two thermometers used in a flow calorimeter should be compared occasionally in stirred water at some convenient temperature and if their indications, after application of the tabular corrections, are found to differ, an additional correction equal to the difference, should be applied, with the proper sign, to the indications of one of them.

NOTE K.—The tabulated corrections apply for a "setting" of 20° C. Setting factors for use with other settings are given on the accompanying sheet.

NOTE L.—The tabulated corrections apply for the condition of immersion indicated provided the ice-point reading, taken after heating to for not less than 3 minutes, is . If the ice-point reading, which should be taken within 5 minutes after removal of the thermometer from the heated bath, is found to be higher (or lower) than stated all other readings will be higher (or lower) to the same extent.

This thermometer was calibrated against standards certified by the National Bureau of Standards.

Standard Serial No. 128239 NBS Identification No. 88024

APPENDIX C

Diatek Oral Probe

Diatek Oral Probe

Identification Number: WHMC 32741

Calibrated: July 25, 1990 by a Certified Biomedical Technician, at Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas, using the Dekabox Decade Resistor DB 62 (Electro Scientific Industrial, Portland, Oregon).

Dekabox Reading	Diatek Reading	Residual
6682 ohms = 98.0°F	98.2°F	+0.2°F
6015 ohms = 98.6°F	98.7°F	+0.1°F
5827 ohms = 100.0°F	100.0°F	0.0°F
5210 ohms = 105.0°F	105.0°F	0.0°F

APPENDIX D

In Vitro Environment Temperature Stability

GLASS MERCURY THERMOMETER TEMPERATURE

	Time in Minutes					
	0	1	2	3	4	5
P.I.	34.1	34.1	34.1	34.1	34.1	34.1
R.A.	34.1	34.1	34.1	34.1	34.1	34.1
P.I.	34.2	34.4	34.4	34.5	34.5	34.5
R.A.	34.2	34.3	34.4	34.5	34.5	34.5
P.I.	34.6	34.7	34.9	34.9	34.9	34.9
R.A.	34.6	34.7	34.8	34.9	34.9	34.9
P.I.	35.0	35.2	35.3	35.4	35.4	35.4
R.A.	35.0	35.1	35.3	35.3	35.4	35.4
P.I.	35.6	35.8	36.0	36.0	36.0	36.1
R.A.	35.6	35.8	35.9	36.0	36.0	36.1
P.I.	36.0	36.2	36.3	36.3	36.4	36.4
R.A.	36.0	36.1	36.2	36.3	36.4	36.4
P.I.	36.4	36.7	36.8	36.9	37.0	37.1
R.A.	36.4	36.7	36.8	36.9	37.0	37.1
P.I.	37.0	37.1	37.3	37.4	37.4	37.4
R.A.	37.0	37.1	37.3	37.4	37.4	37.4
P.I.	37.5	37.7	37.9	37.9	38.0	38.0
R.A.	37.5	37.7	37.8	37.9	38.0	38.0
P.I.	38.0	38.2	38.3	38.4	38.4	38.4
R.A.	38.0	38.2	38.3	38.4	38.4	38.4
P.I.	38.4	38.7	38.9	39.0	39.0	39.0
R.A.	38.5	38.7	38.9	39.0	39.0	39.0
P.I.	39.0	39.2	39.3	39.4	39.4	39.5
R.A.	39.0	39.2	39.3	39.4	39.5	39.5
P.I.	39.5	39.7	39.8	39.9	39.9	39.9
R.A.	39.5	39.7	39.8	39.9	39.9	39.9

P.I. = Primary Investigator **R.A.** = Research Assistant

APPENDIX E

FirstTemp^{R} Infrared Tympanic Thermometer Model 2000A

ITT A (FirstTemp^{R} by Intelligent Medical Systems)
Model: 2000A
Serial Number: 23344
Calibration: By Intelligent Medical Systems

ITT B (FirstTemp^{R} by Intelligent Medical Systems)
Model: 2000A
Serial Number: 30616
Calibration: By Intelligent Medical Systems

Accuracy Specification for Model 2000A: $\pm$ 0.2^{o}F ($\pm$ 0.1^{o}C) 96^{o} - 102^{o}F. Other points as specified by ASTM.

OPERATION INSTRUCTIONS

1. Put ITT on the plugged-in charger base. Turn it on by using the on/off switch on the back of the unit and sliding it toward the red dot.

2. Allow ITT to warm up and stabilize for 30 minutes prior to first use.

3. Select **TYMPANIC** mode.

4. Select **COR** equivalence setting. Temperature is adjusted to approximate core (tympanic) temperature measurement.

5. Select **CENTIGRADE** temperature scale display.

6. Lock (inhibit) the changing of mode, equivalence and scale.

7. Remove from charger and wait for **READY** to appear on display. (Device always shows "NOT READY" when on charger).

8. Grasp probe at finger grips and lift from cradle.

9. Place disposable probe cover on probe.

10. Place probe at artificial auditory canal in water bath and seal external opening.

11. Press **SCAN** button on probe handle.

12. Wait for intermittent beep to sound and red light to illuminate on probe (1 - 2 seconds).

13. Read temperature on display screen. Record temperature.

14. Press blue **RELEASE** button to discard probe cover.

15. Replace probe in cradle.

APPENDIX F

In Vitro Environment

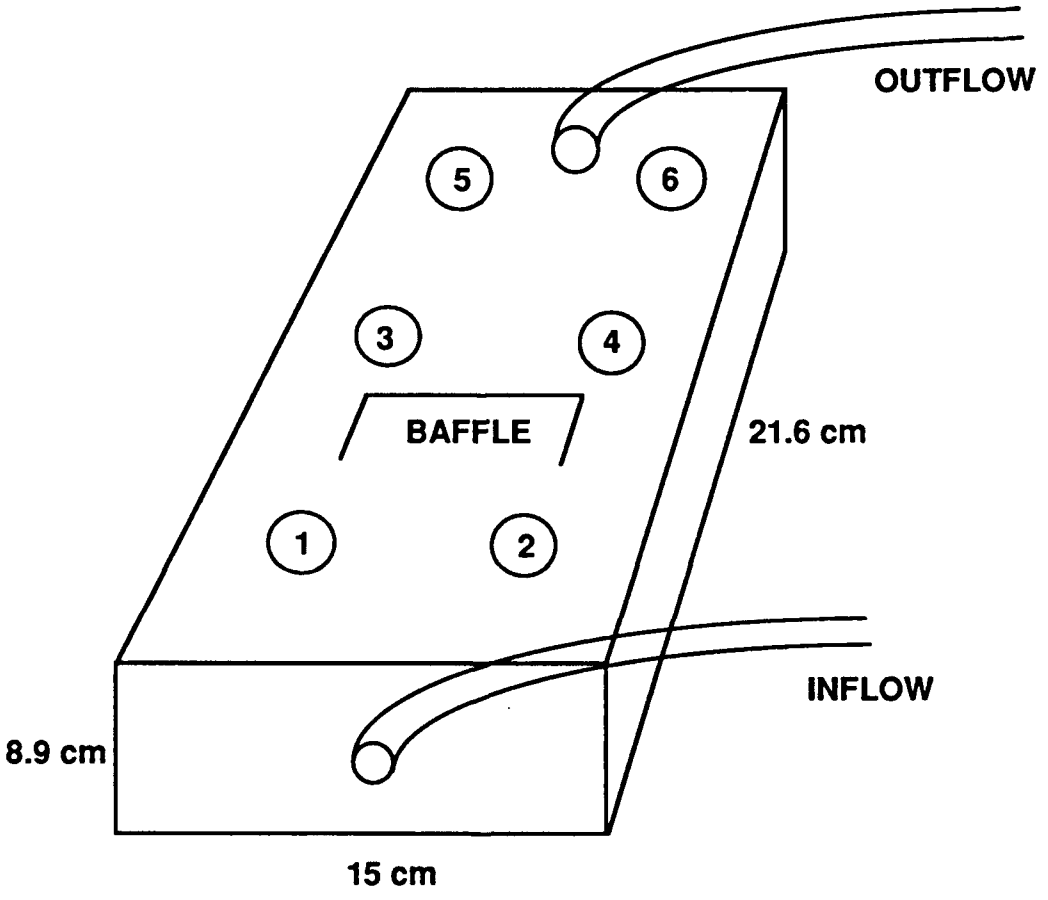
IN VITRO ENVIRONMENT

1 and 2 - Diatek Oral Probe Ports

3 and 4 - Glass Mercury Thermometer Ports

5 and 6 - Infrared Tympanic Thermometer Ports

Inflow and Outflow tubing was connected to the Fisher Scientific Isotemp Refrigerated Circulator Model 9000



APPENDIX G

Fisher Scientific Isotemp Refrigerated Circulator Model 9000

FISHER SCIENTIFIC ISOTEMP REFRIGERATED CIRCULATOR MODEL 9000

IDENTIFICATION NUMBER 32329
SERIAL NUMBER 860756

115 V 60 Cycle Hz
Calibrated every 6 months from Oct. 1988 - March 1990.

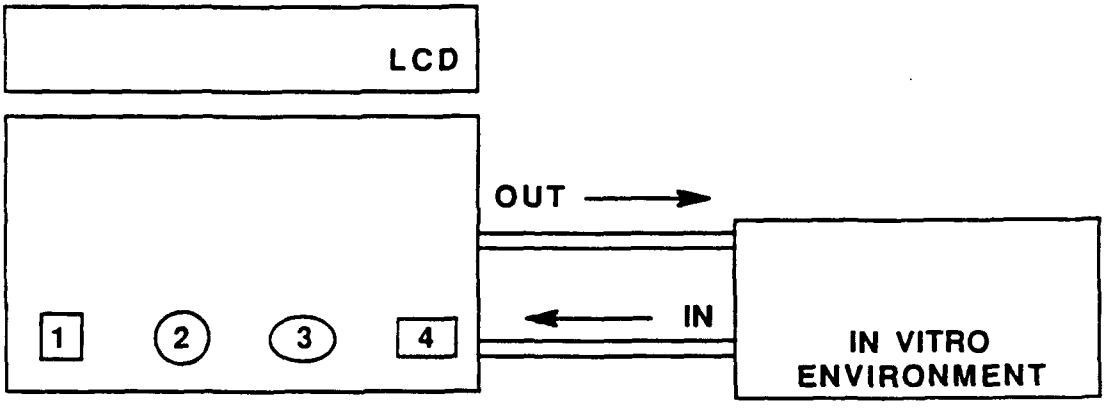
LCD = LIQUID CRYSTAL DISPLAY

1 = TEMPERATURE SETTING

2 = TEMPERATURE ADJUSTMENT

3 = COOLING ON

4 = POWER ON



APPENDIX H

Raw Data

LEGEND

GMT = GLASS MERCURY THERMOMETER CENTIGRADE
GMTF = GLASS MERCURY THERMOMETER FAHRENHEIT
ITTA = INFRARED TYMPANIC THERMOMETER A CENTIGRADE
ITTAF = INFRARED TYMPANIC THERMOMETER A FAHRENHEIT
ITTB = INFRARED TYMPANIC THERMOMETER B CENTIGRADE
ITTBF = INFRARED TYMPANIC THERMOMETER B FAHRENHEIT
ORAL = DIATEK ORAL PROBE CENTIGRADE
ORALF = DIATEK ORAL PROBE FAHRENHEIT

*RAW DATA WAS COLLECTED USING THE CENTIGRADE SCALE. THE RAW DATA WAS CONVERTED TO FAHRENHEIT USING THE FORMULA ((^{O}C) * (9/5) + 32).

PROTOCOL 1

GMT	GMTF	ITTA	ITTAF	ITTB	ITTBF	ORAL	ORALF
34.1	93.38	34.4	93.92	34.4	93.92	34.2	93.56
34.1	93.38	34.6	94.28	34.2	93.56	34.2	93.56
34.1	93.38	34.7	94.46	34.4	93.92	34.2	93.56
34.5	94.10	34.9	94.82	34.5	94.10	34.6	94.28
34.5	94.10	34.9	94.82	34.6	94.28	34.6	94.28
34.5	94.10	35.0	95.00	34.8	94.64	34.6	94.28
35.0	95.00	35.6	96.08	34.8	94.64	35.1	95.18
35.0	95.00	35.6	96.08	35.3	95.54	35.2	95.36
35.0	95.00	35.5	95.90	35.1	95.18	35.2	95.36
35.5	95.90	35.9	96.62	35.6	96.08	35.6	96.08
35.5	95.90	36.1	96.98	35.6	96.08	35.6	96.08
35.5	95.90	36.1	96.98	35.6	96.08	35.7	96.26
35.9	96.62	36.5	97.70	36.1	96.98	36.0	96.80
35.9	96.62	36.6	97.88	36.1	96.98	36.1	96.98
35.9	96.62	36.7	98.06	36.0	96.80	36.1	96.98
36.5	97.70	37.2	98.96	36.5	97.70	36.6	97.88
36.5	97.70	37.1	98.78	36.4	97.52	36.6	97.88
36.5	97.70	37.4	99.32	36.7	98.06	36.7	98.06
37.0	98.60	37.4	99.32	36.9	98.42	37.1	98.78
37.0	98.60	37.6	99.68	36.9	98.42	37.1	98.78
37.0	98.60	37.5	99.50	37.0	98.60	37.1	98.78
37.5	99.50	37.9	100.22	37.4	99.32	37.6	99.68
37.5	99.50	38.0	100.40	37.5	99.50	37.6	99.68
37.5	99.50	38.0	100.40	37.5	99.50	37.7	99.86
38.0	100.40	38.4	101.12	37.9	100.22	38.1	100.58
38.0	100.40	38.4	101.12	37.8	100.04	38.1	100.58
38.0	100.40	38.4	101.12	38.1	100.58	38.1	100.58
38.4	101.12	38.8	101.84	38.4	101.12	38.5	101.30
38.4	101.12	38.7	101.66	38.2	100.76	38.6	101.48
38.4	101.12	38.9	102.02	38.1	100.58	38.6	101.48
39.0	102.20	39.5	103.10	38.8	101.84	39.1	102.38
39.0	102.20	39.5	103.10	39.1	102.38	39.2	102.56
39.0	102.20	39.7	103 46	39.1	102.38	39.2	102.56
39.5	103.10	40.1	104.18	39.5	103.10	39.7	103.46
39.5	103.10	40.0	104.00	39.6	103.28	39.7	103.46
39.5	103.10	39.9	103.82	39.4	102.92	39.7	103.46
40.0	104.00	40.3	104.54	39.6	103.28	40.1	104.18
40.0	104.00	40.3	104.54	39.8	103.64	40.2	104.36
40.0	104.00	40.4	104.72	39.8	103.64	40.2	104.36

PROTOCOL 2

GMT	GMTF	ITTA	ITTAF	ITTB	ITTBF	ORAL	ORALF
34.0	93.20	34.4	93.92	34.2	93.56	34.2	93.56
34.0	93.20	34.7	94.46	34.1	93.38	34.2	93.56
34.0	93.20	34.7	94.46	34.2	93.56	34.2	93.56
34.5	94.10	35.0	95.00	34.5	94.10	34.6	94.28
34.5	94.10	35.0	95.00	34.6	94.28	34.7	94.46
34.5	94.10	35.1	95.18	34.7	94.46	34.7	94.46
35.0	95.00	35.7	96.26	35.1	95.18	35.1	95.18
35.0	95.00	35.6	96.08	35.2	95.36	35.2	95.36
35.0	95.00	35.7	96.26	35.2	95.36	35.2	95.36
35.5	95.90	35.9	96.62	35.4	95.72	35.6	96.08
35.5	95.90	36.0	96.80	35.6	96.08	35.6	96.08
35.5	95.90	36.1	96.98	35.7	96.26	35.7	96.26
36.0	96.80	36.5	97.70	36.0	96.80	36.1	96.98
36.0	96.80	36.5	97.70	36.1	96.98	36.2	97.16
36.0	96.80	36.5	97.70	36.1	96.98	36.2	97.16
36.5	97.70	36.9	98.42	36.4	97.52	36.6	97.88
36.5	97.70	36.9	98.42	36.5	97.70	36.6	97.88
36.5	97.70	37.0	98.60	36.5	97.70	36.6	97.88
37.0	98.60	37.2	98.96	37.1	98.78	37.2	98.96
37.0	98.60	37.4	99.32	37.1	98.78	37.2	98.96
37.0	98.60	37.5	99.50	37.0	98.60	37.2	98.96
37.4	99.32	37.7	99.86	37.5	99.50	37.6	99.68
37.4	99.32	37.8	100.04	37.5	99.50	37.6	99.68
37.4	99.32	38.0	100.40	37.4	99.32	37.6	99.68
38.1	100.58	38.3	100.94	38.1	100.58	38.2	100.76
38.1	100.58	38.5	101.30	38.0	100.40	38.3	100.94
38.1	100.58	38.4	101.12	38.0	100.40	38.3	100.94
38.4	101.12	38.7	101.66	38.3	100.94	38.6	101.48
38.4	101.12	39.0	102.20	38.3	100.94	38.6	101.48
38.4	101.12	38.8	101.84	38.4	101.12	38.6	101.48
39.0	102.20	39.2	102.56	38.9	102.02	39.1	102.38
39.0	102.20	39.3	102.74	38.7	101.66	39.1	102.38
39.0	102.20	39.3	102.74	38.9	102.02	39.2	102.56
39.5	103.10	39.7	103.46	39.4	102.92	39.6	103.28
39.5	103.10	39.6	103.28	39.3	102.74	39.7	103.46
39.5	103.10	39.8	103.64	39.5	103.10	39.7	103.46
39.9	103.82	40.2	104.36	39.8	103.64	40.1	104.18
39.9	103.82	40.1	104.18	39.8	103.64	40.1	104.18
39.9	103.82	40.2	104.36	39.8	103.64	40.1	104.18

REFERENCES

Baker, M., Stocking, R., & Meehan, J. (1972). Thermal relationship between tympanic membrane and hypothalamus in conscious cat and monkey. Journal of Applied Physiology, 32, 739-742.

Baker, N., Cerone, S., Gaze, N., & Knapp, T. (1984). The effect of type of thermometer and length of time inserted on oral temperature measurements of afebrile subjects. Nursing Research, 33(2), 109-111.

Ballenger, J. (1985). Diseases of the nose, throat, ear, head and neck (13th ed.). Philadelphia: Lea & Febiger.

Barber, , & Kilmon, C. (1989). Reactions to tympanic temperature measurement in an ambulatory setting. Pediatric Nursing, 15, 477-480.

Benzinger, M. (1969). Tympanic thermometry in surgery and anesthesia. Journal of the American Medical Association, 209, 1207-1211.

Benzinger, T. (1969). Clinical temperature. Journal of the American Medical Association, 209, 1200-1206.

Benzinger, T. (1963). Cranial measurements of internal temperature in man. In J. Hardy (Ed.), Temperature: It's Measurement and Control in Science and Industry (pp. 111-120). New York: Reinhold Publishing.

Bligh, J. (1973). The temperatures of the body and their thermoregulatory significance. In J. Bligh (Ed.), Temperature Regulation in Mammals and Other Vertebrates (pp. 77-93). New York: American Elsevier.

Bordley, J., Brookhouser, P., & Tucker, G. (1986). Ear, nose, and throat disorders in children. New York: Raven Press.

Cooper, K., Cranston, W., & Snell, E. (1964). Temperature in the external auditory meatus as an index of central temperature changes. Journal of Applied Physiology, 19, 1032-1035.

Erickson, R. (1990). Comparison of tympanic and oral temperatures. Heart & Lung, 19(3), 305. (From NTI Research Abstracts).

Erickson, R. (1980). Oral temperature differences in relation to thermometer and technique. Nursing Research, 29(3), 157-164.

Fisch, R., Eaton, B., & Giebink, G. (1982). Tympanic membrane temperature during experimental otitis media due to streptococcus pneumoniae in chinchillas. Laboratory Animal Science, 32, 278-279.

Forster, B., Adler, D., & Davis, M. (1970). Duration of effects of iced water on oral temperature. Nursing Research, 19(2), 169-170.

Gassert, C. (1990). Reliability and validity of physiologic measurement. Critical Care Nurse Quarterly, 12(4), 17-20.

Gift, A., & Soeken, K. (1988). Assessment of physiologic instruments. Heart and Lung, 17(2), 128-133.

Guyton, A. (1986). Textbook of medical physiology (7th ed.). Philadelphia: Saunders.

Kinney, M., Packa, D., & Dunbar, S. (1988). AACN's clinical reference for critical-care nurses (2nd ed.). (p. 415). New York: McGraw-Hill.

LoBiondo-Wood, G., & Haber, J. (1990). Nursing research: Methods, critical appraisal, and utilization (2nd ed.). (p. 304). Philadelphia: C.V. Mosby.

Morris, W. (1976). The American heritage dictionary of the English language (p. 689). Boston: Houghton Mifflin Co.

Munro, B., Visintainer, M., & Page, E. (1986). Statistical methods for health care research (p. 64). Philadelphia: Lippincott.

Nadel, E., & Horvath, S. (1970). Comparison of tympanic membrane and deep body temperatures in man. Life Sciences, 9(1), 869-875.

Polit, F. & Hungler, R. (1987). Nursing Research: Principles and Methods (3rd ed.). (p. 313). Philadelphia: Lippincott.

Ros, S. (1989). Evaluation of a tympanic membrane thermometer in an outpatient clinical setting. Annals of Emergency Medicine, 18, 1004-1006.

Shellock, F., & Rubin, S. (1982). Simplified and highly accurate core temperature measurements. Medical Progress through Technology, 8, 187-188.

Shinozaki, T., Deane, R., & Perkins, F. (1988). Infrared tympanic thermometer: Evaluation of a new clinical thermometer. Critical Care Medicine, 16(2), 148-150.

Shiraki, K., Konda, N., & Sagawa, S. (1986). Esophageal and tympanic temperature responses to core blood temperature changes during hyperthermia. Journal of Applied Physiology, 16(1), 98-102.

Terndrup, T., Allegra, J., & Kealy, J. (1989). A comparison of oral, rectal and tympanic-membrane derived temperature changes after ingestion of liquids and smoking. American Journal of Emergency Medicine, 7(2), 150-154.

Wallace, C., Marks, W., Adkins, W., & Mahaffey, J. (1974). Perforation of the tympanic membrane, a complication of tympanic thermometry during anesthesia. Anesthesiology, 41(3), 290-291.

Webb, G. (1973). Comparison of esophageal and tympanic temperature monitoring during cardiopulmonary bypass. Journal of the International Anesthesia Research Society, 52(5), 729-733.

Williams, P., Warwick, R., Dyson, M., & Bannister, L. (1989). Gray's anatomy (37th ed.). New York: Churchill Livingstone.

Wilson, R., Knapp, C., Traber, D., & Priano, L. (1971). Tympanic thermography: A clinical and research evaluation of a new technic. Southern Medical Journal, 64(12), 1452-1455.

Woodman, E., Parry, S., & Simms, L. (1967). Sources of unreliability in oral temperatures. Nursing Research, 16(3), 276-279.